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**Agenda for Quarterly Meeting on  
MDUFA V (FY 2023-2027) Performance  
May 30, 2025, 1:00 – 2:00 pm  
Teams**

**Welcome –**

**FDA MDUFA Performance — Actions through March 31, 2025**

- Report on performance goals for 2<sup>nd</sup> Quarter FY 2025

**Guidance Development**

**Registration and Listing**

**Qualitative Update on Finances – 2nd Quarter FY 2025**

- User fee receipts through the 2nd Quarter

**Annual Hiring Goals Update**

**Quality Management Update**

- Call for Proposals

**ASCA Program Update**



**Quarterly Update on  
Medical Device Performance Goals  
---- MDUFA V CDRH Performance Data ----  
Actions through 31 March 2025**



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### ***Acronyms and Abbreviations***

510(k)	Premarket Notification
CDRH	Center for Devices and Radiologic Health
CLIA	Clinical Laboratory Improvement Amendments
IDE	Investigational Device Exemption
IVD	In Vitro Diagnostic
LDT	Laboratory Developed Test
MDUFA	Medical Device User Fee Act
NSE	Not Substantially Equivalent
PMA	Premarket Application
RTA	Refuse to Accept
RTF	Refuse to File
SE	Substantially Equivalent
SI	Substantive Interaction

### ***Office Organizations***

OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device

OHT2: Office of Cardiovascular Devices

OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices

OHT4: Office of Surgical and Infection Control Devices

OHT5: Office of Neurological and Physical Medicine Devices

OHT6: Office of Orthopedic Devices

OHT7: Office of In Vitro Diagnostics

OHT8: Office of Radiological Health

**Note: Data may change in subsequent quarterly and annual reports.**

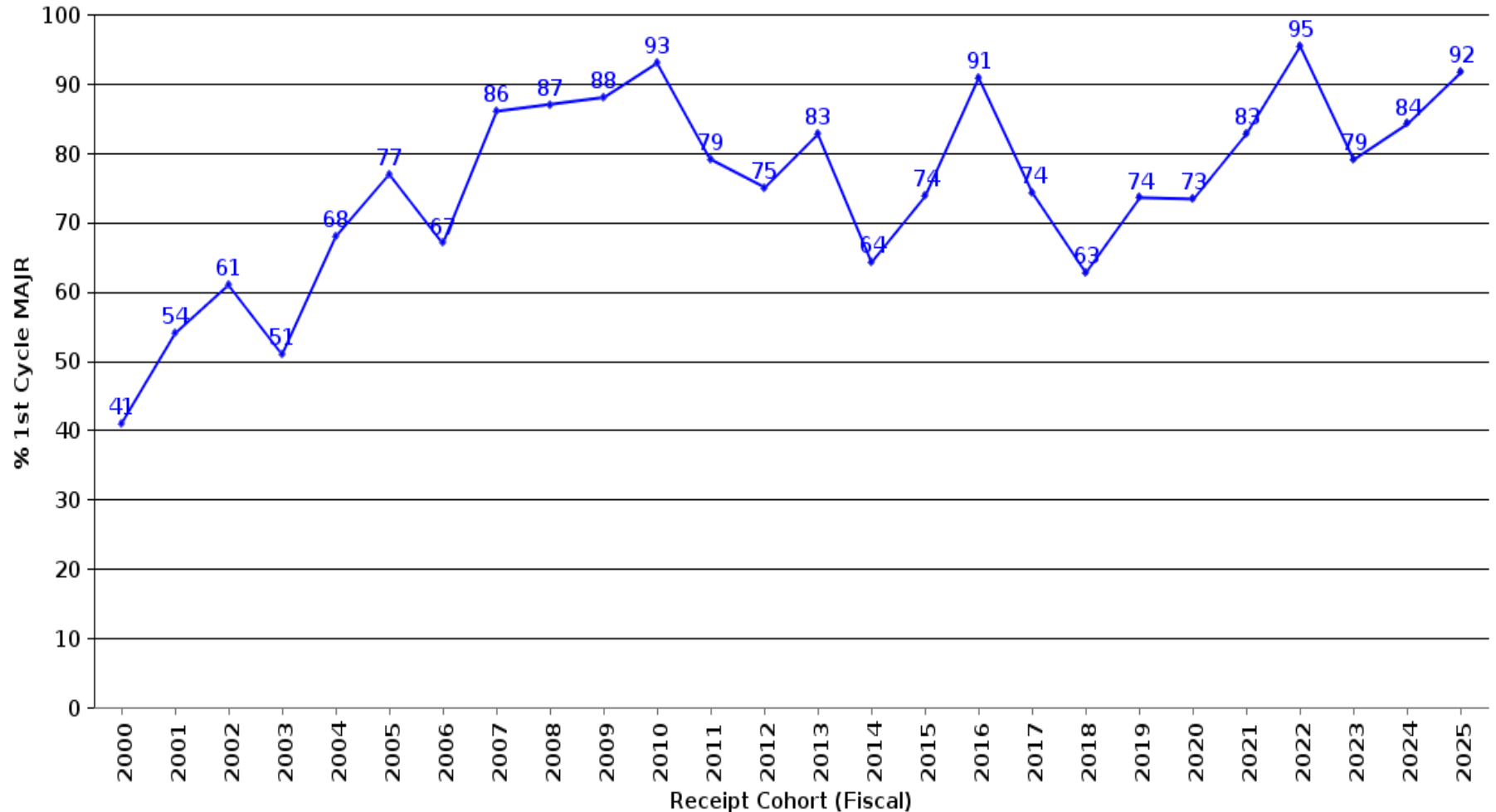


# PMA's

## Q2FY2025



## PMA Originals Filed As Of 12/31/24: 1st Cycle Major Deficiency Rate as of 3/31/25



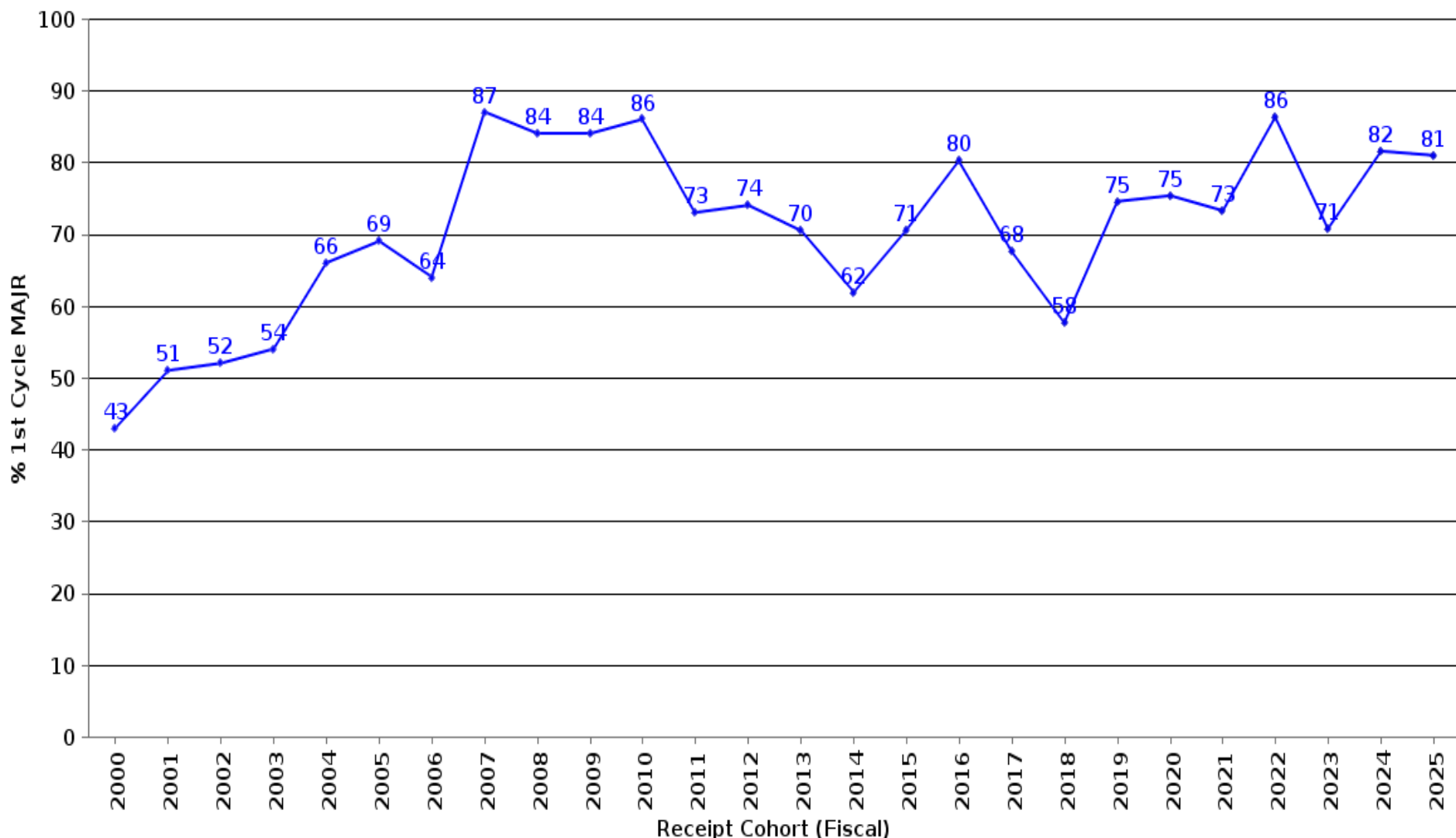
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 12/31/24.

Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

◆ % 1st Cycle MAJR PMAO



PMA Originals and Panel Track Supplements Filed As Of 12/31/24: 1st Cycle Major Deficiency Rate as of 3/31/25

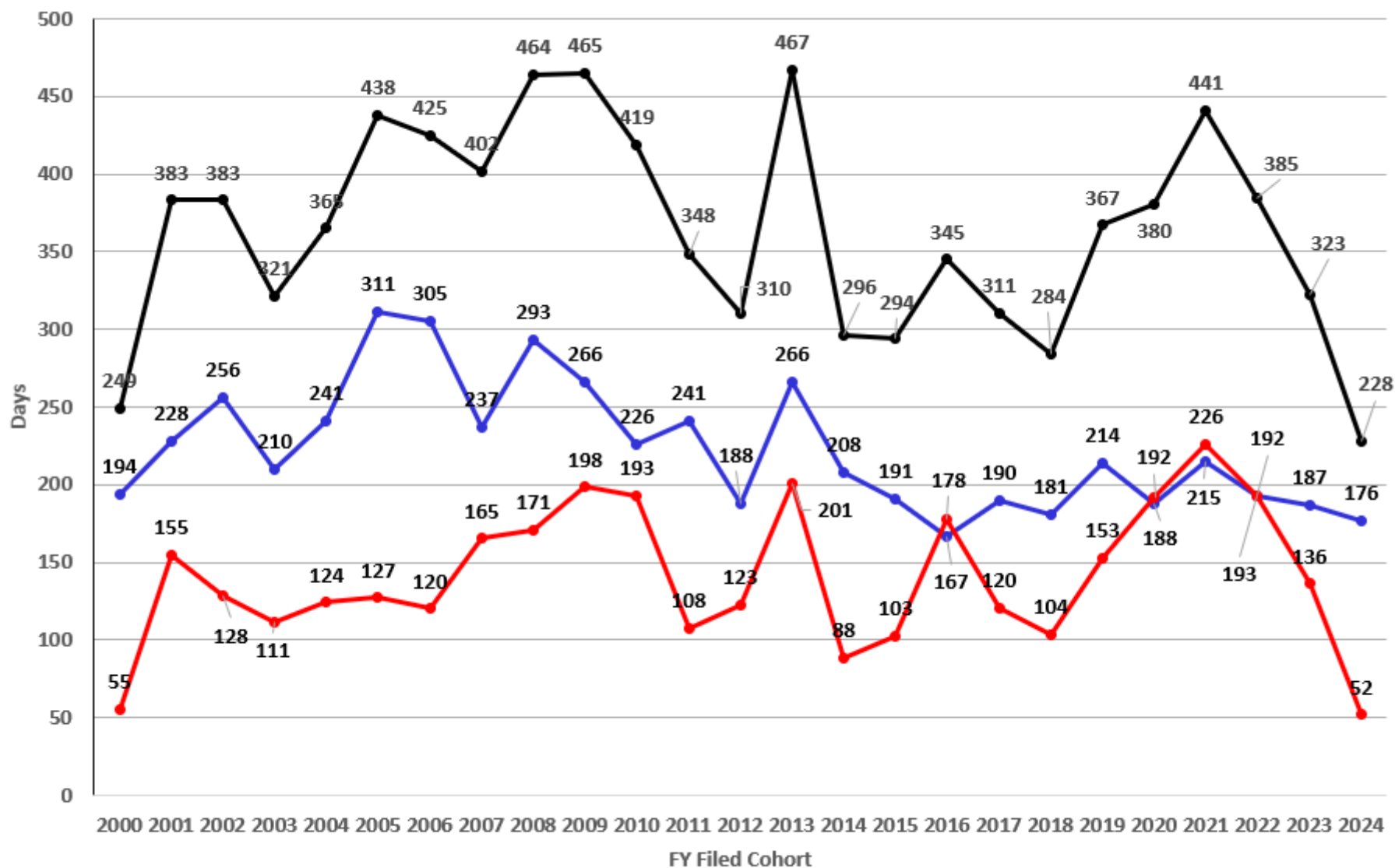


Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 12/31/24. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

◆ % 1st Cycle MAJR PMAO/PTS



## PMA Originals Filed As Of 3/31/2025: Average Time to MDUFA Decision



—●— Avg FDA Days to MDUFA Decision

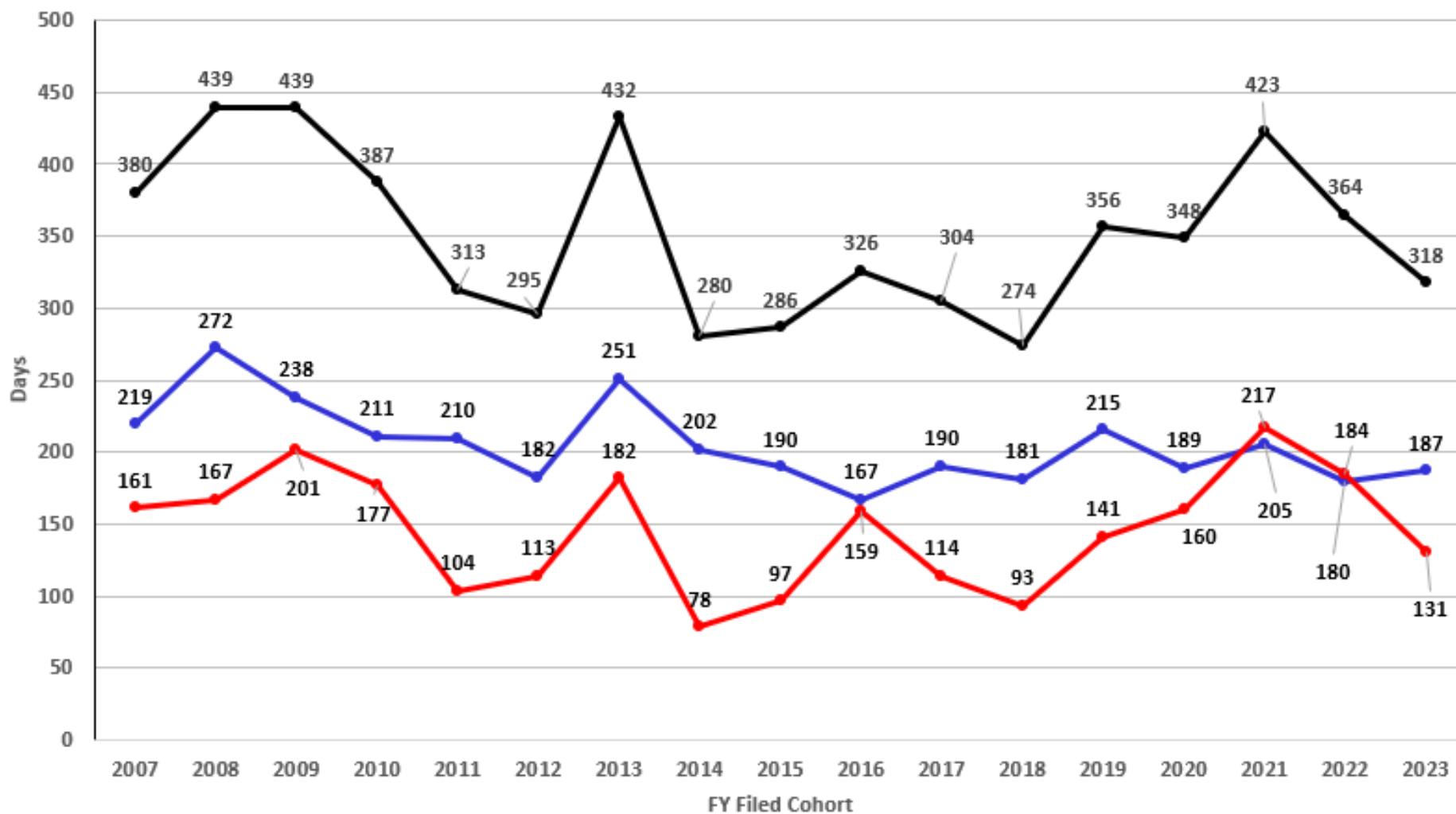
—●— Avg MFR Days to MDUFA Decision

—●— Avg Total Days to MDUFA Decision



# PMA Originals Filed As Of 3/31/2025: Average Time to MDUFA Decision

Comparison of Cohorts at 97.67% Closure

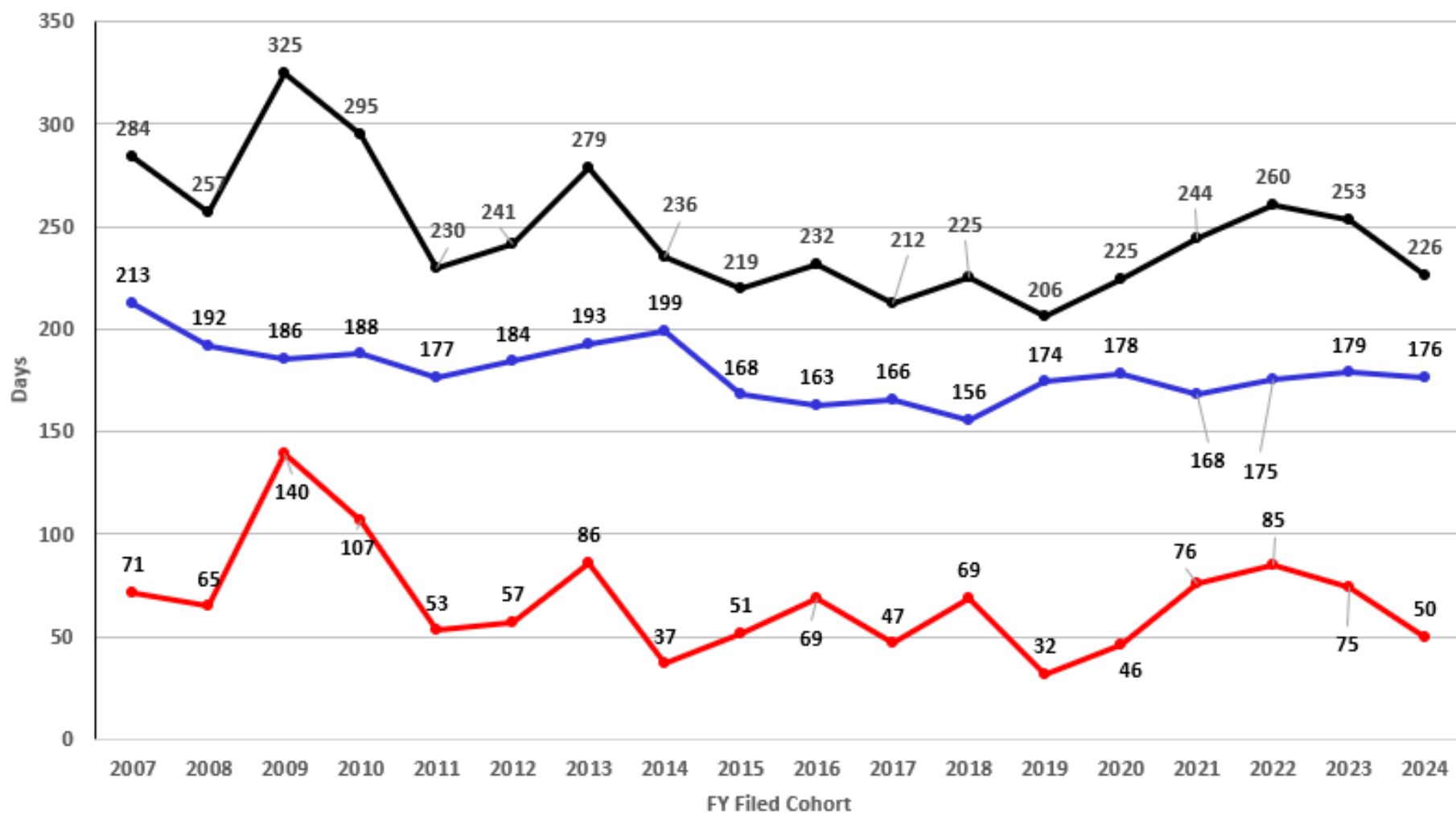


● Avg FDA Days to MDUFA Decision 
 ● Avg MFR Days to MDUFA Decision 
 ● Avg Total Days to MDUFA Decision



# PMA Originals Filed As Of 3/31/2025: Average Time to MDUFA Decision

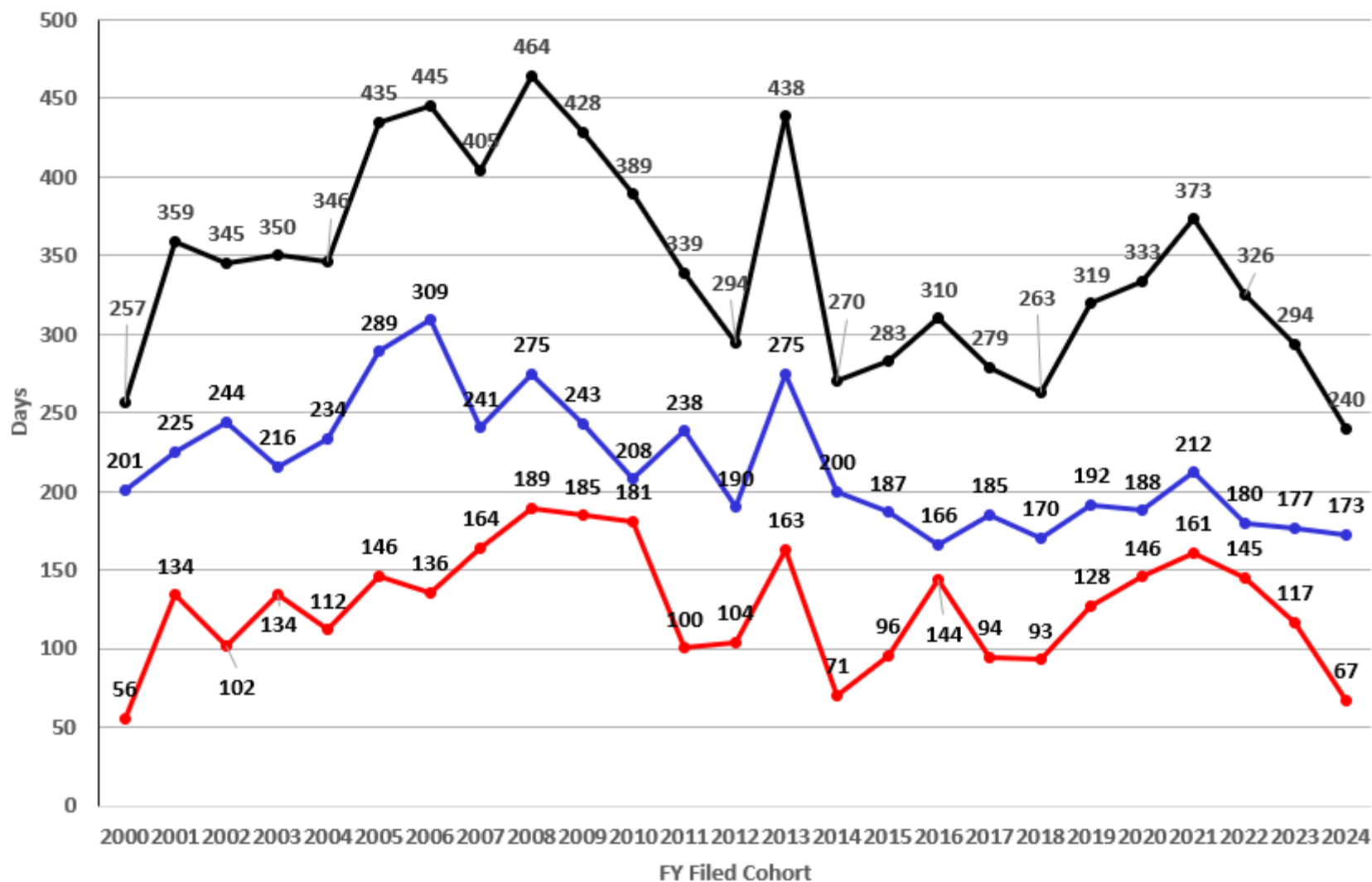
Comparison of Cohorts at 51.28% Closure



—●— Avg FDA Days to MDUFA Decision —●— Avg MFR Days to MDUFA Decision —●— Avg Total Days to MDUFA Decision



PMA Originals and Panel Track Supplements Filed as of 3/31/2025: Average Time to MDUFA Decision

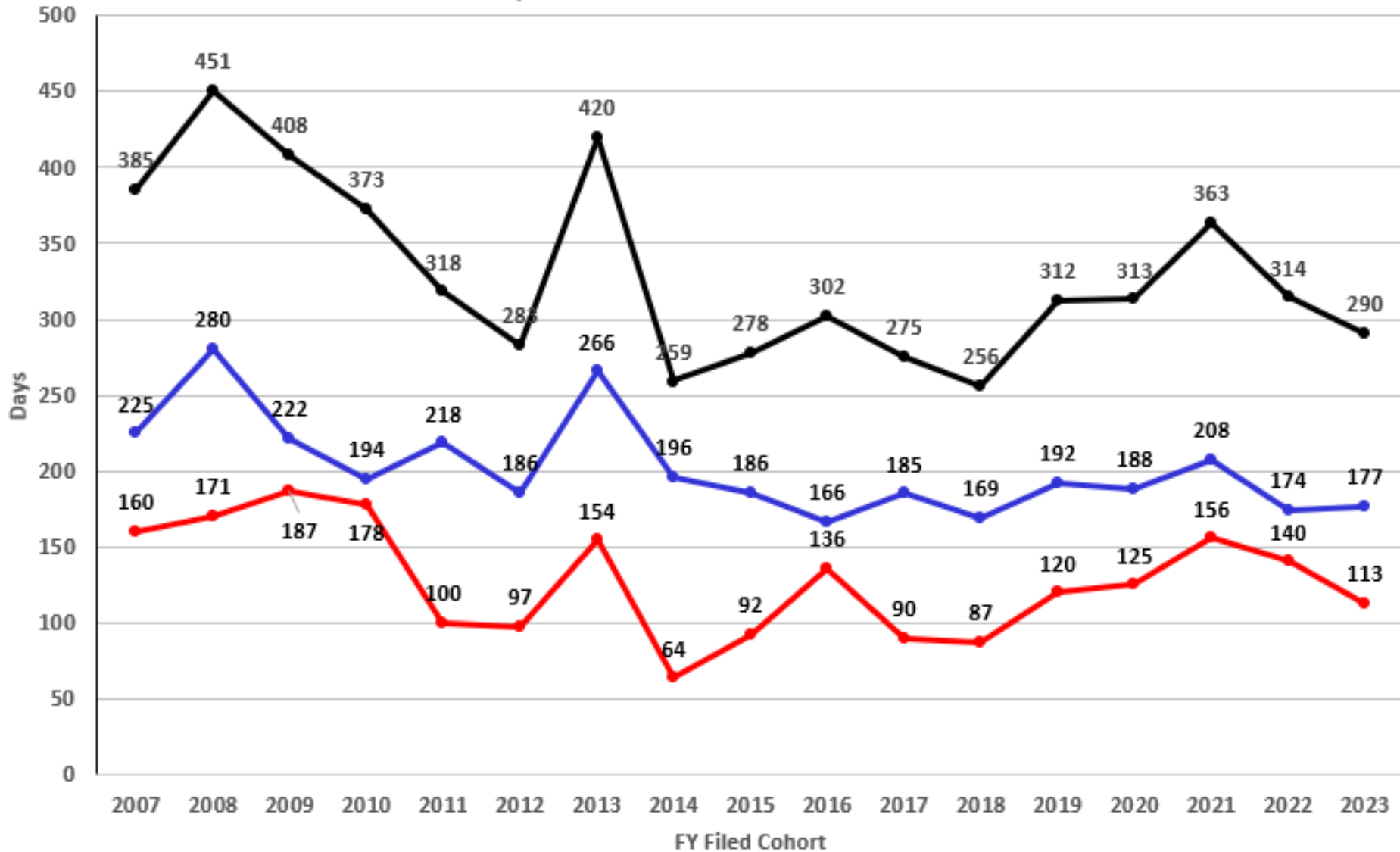


Cohorts not yet closed: 2023: 98.61%; 2024: 55.38%

— Avg FDA Days to MDUFA PMAO-PTS — Avg MFR Days to MDUFA PMAO-PTS — Avg Total Days to MDUFA PMAO-PTS



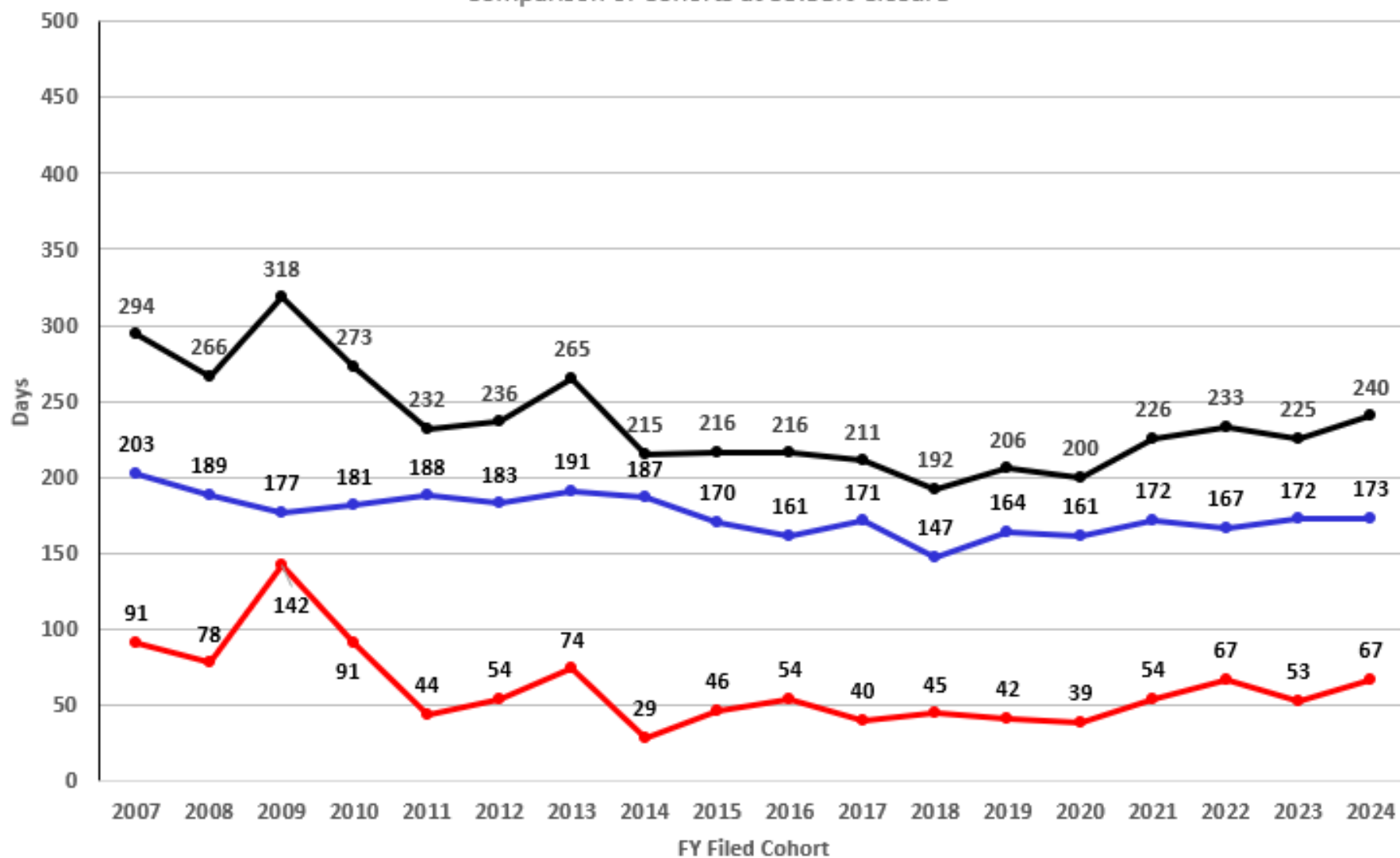
PMA Originals and Panel Track Supplements Filed as of 3/31/2025: Average Time to MDUFA Decision  
Comparison of Cohorts at 98.61% Closure



—●— Avg FDA Days to MDUFA PMAO-PTS 
 —●— Avg MFR Days to MDUFA PMAO-PTS 
 —●— Avg Total Days to MDUFA PMAO-PTS



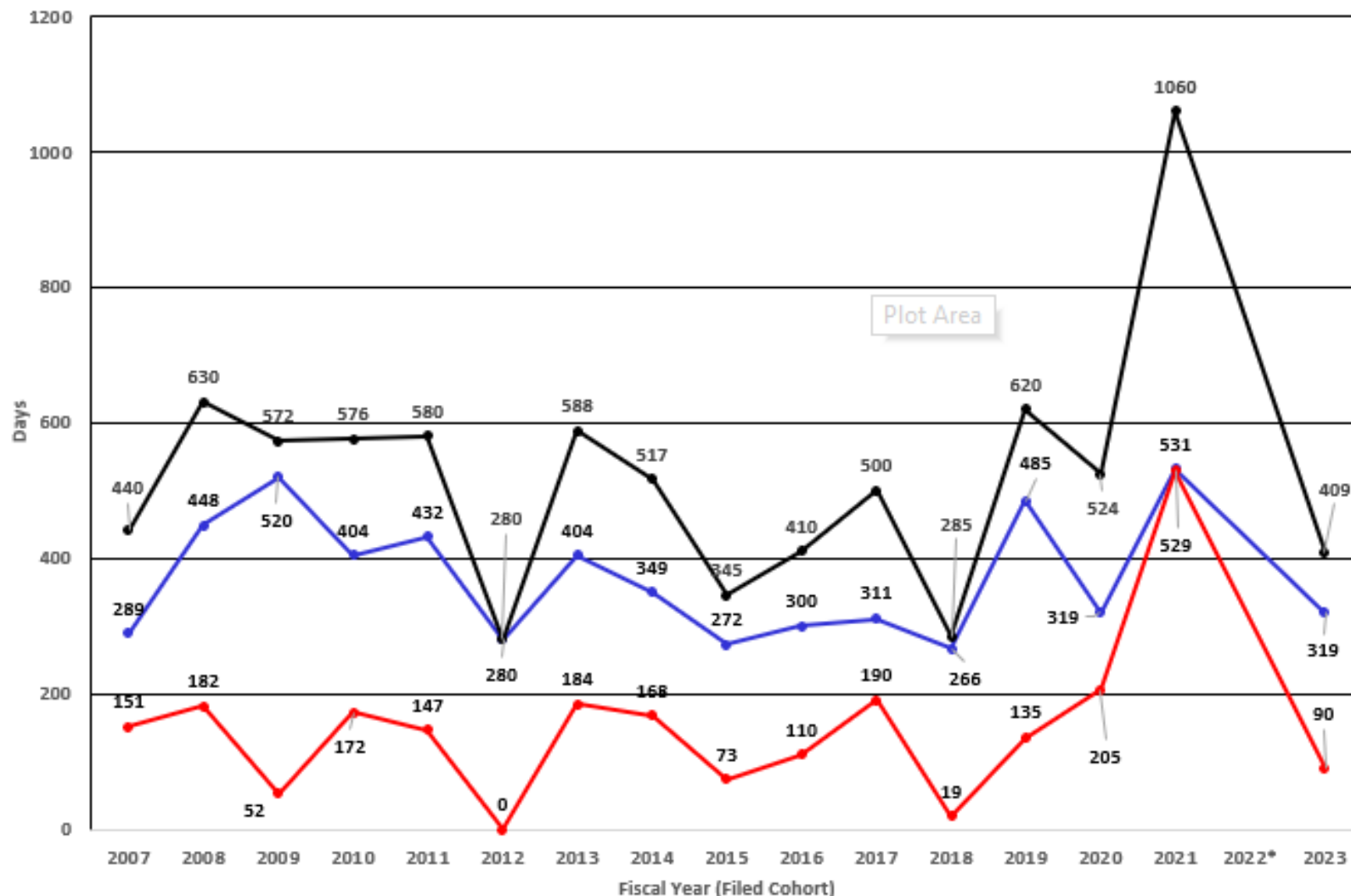
PMA Originals and Panel Track Supplements Filed as of 3/31/2025: Average Time to MDUFA Decision  
Comparison of Cohorts at 55.38% Closure



— Avg FDA Days to MDUFA PMAO-PTS — Avg MFR Days to MDUFA PMAO-PTS — Avg Total Days to MDUFA PMAO-PTS



**PMA Originals With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of:  
3/31/2025**

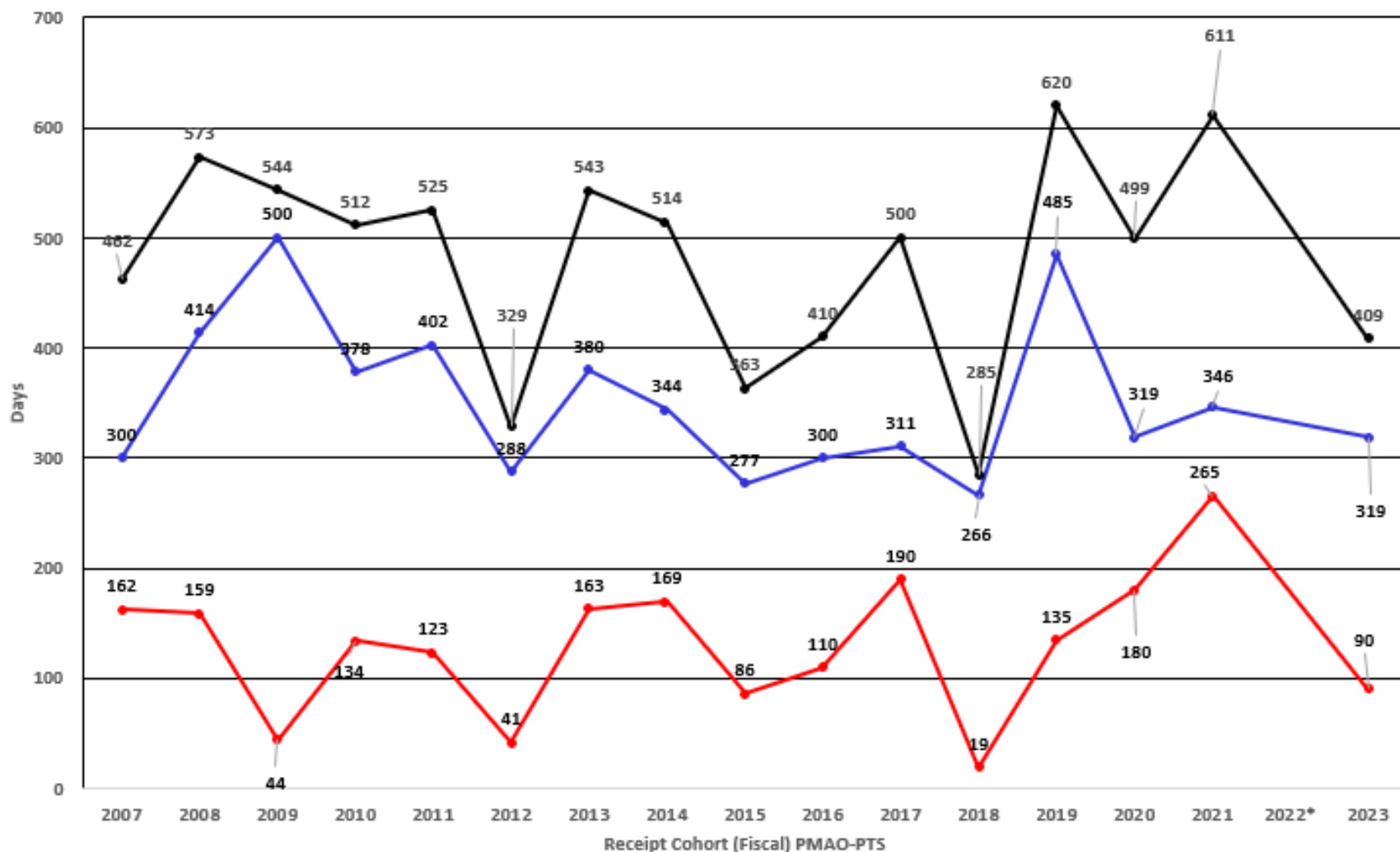


Numbers Closed/Filed: 2007 = 7/7; 2008 = 7/7; 2009 = 6/6; 2010 = 7/7; 2011 = 11/11; 2012 = 1/1; 2013 = 11/11;  
2014 = 5/5; 2015 = 5/5; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 3/3; 2021 = 1/1; 2023 = 4/4

\*Note: For FY22, there were no applicable MDUFA decisions for PMA Originals with Panel Review



**PMA Originals and Panel Track Supplements With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 3/31/2025**



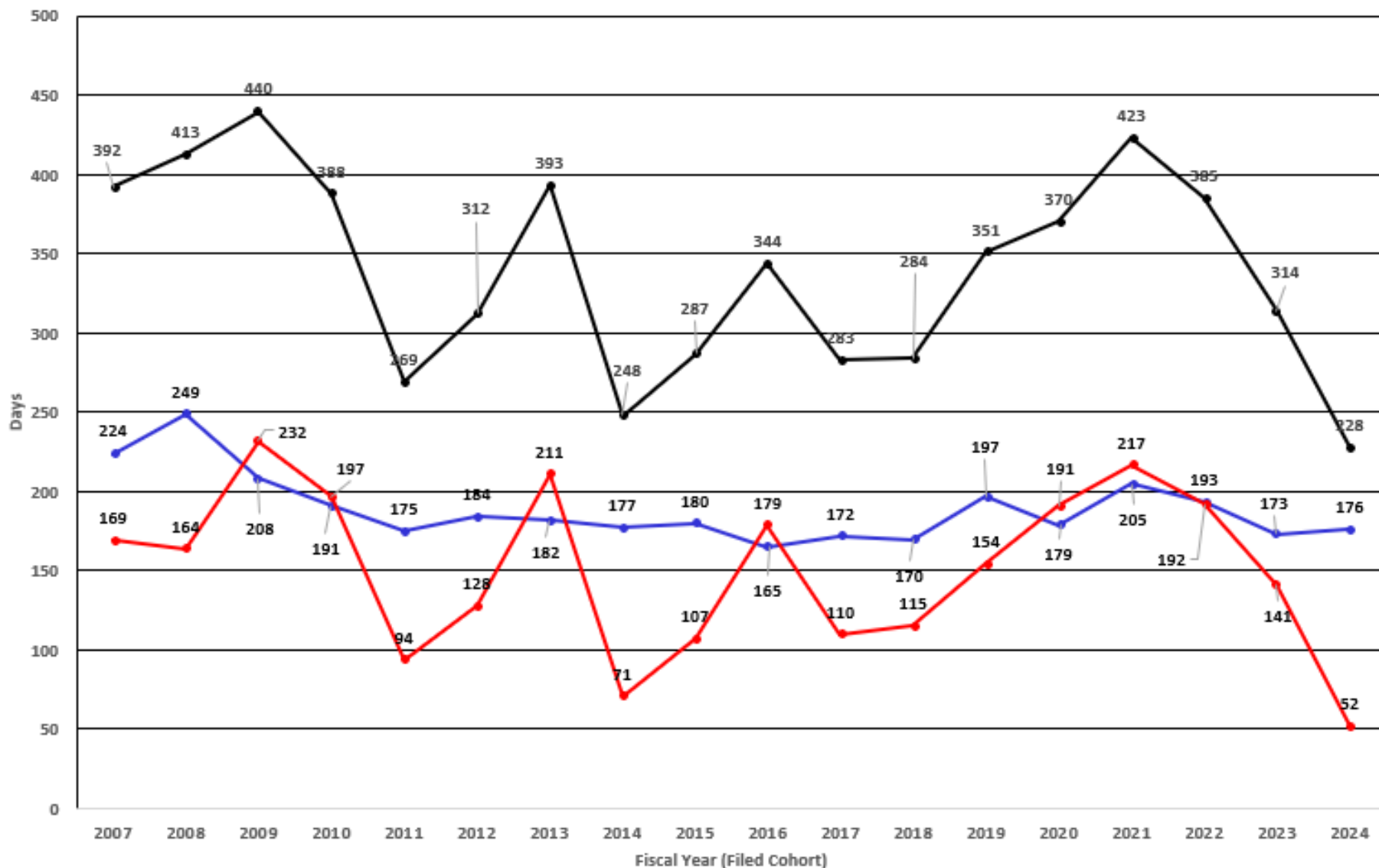
Numbers Closed/Filed: 2007 = 8/8; 2008 = 8/8; 2009 = 7/7; 2010 = 9/9; 2011 = 14/14; 2012 = 2/2; 2013 = 17/17; 2014 = 6/6; 2015 = 6/6; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 4/4; 2021 = 2/2; 2023 = 4/4

\*Note: For FY22, there were no applicable MDUFA decisions for PMA Originals and Panel Track Supplements with Panel Review

— Avg FDA Days to MDUFA Decision PMAO-PTS — Avg MFR Days to MDUFA Decision PMAO-PTS — Avg Total Days to MDUFA Decision PMAO-PTS



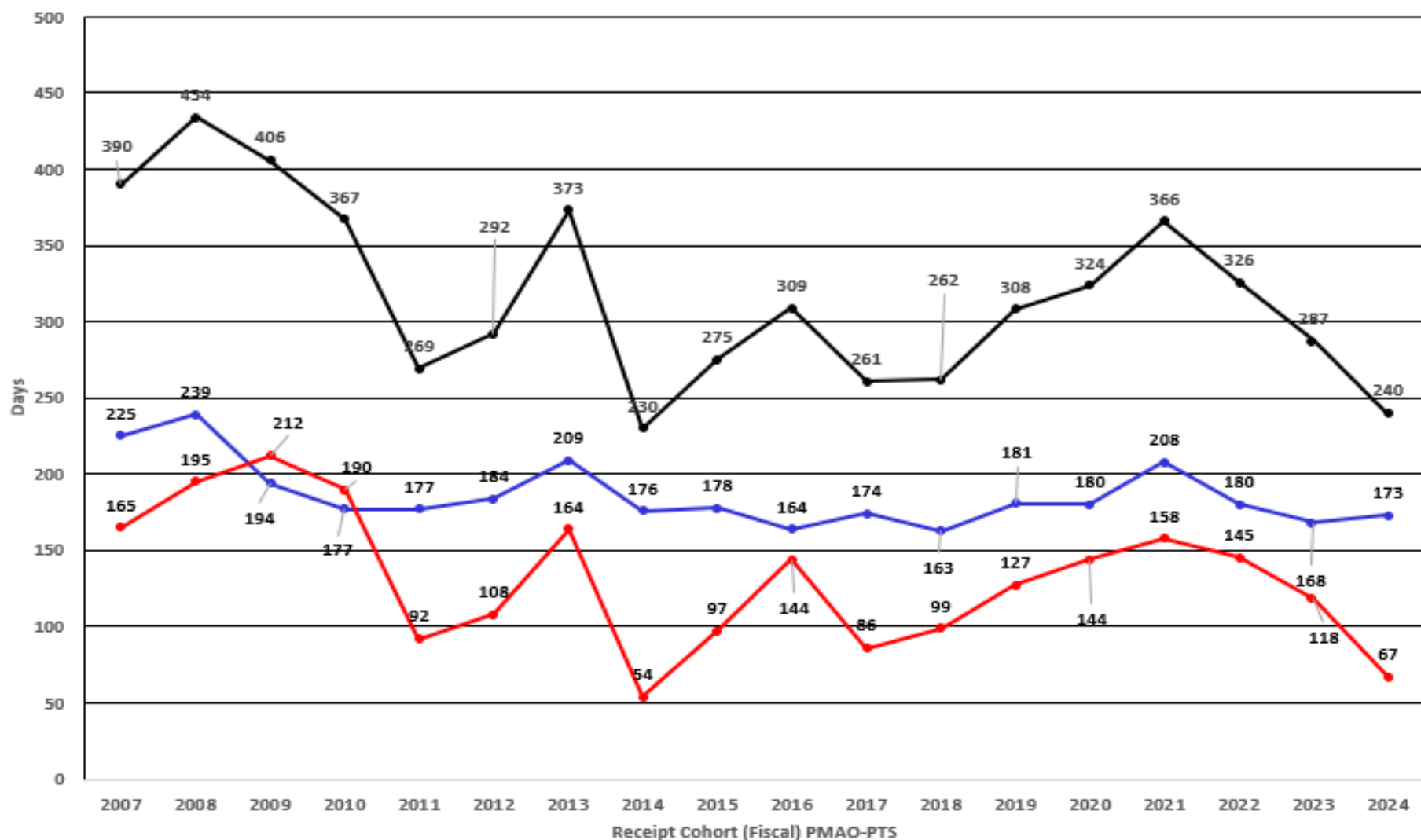
# PMA Originals Without Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 3/31/2025



Numbers Closed/Filed: 2007 = 28/28; 2008 = 23/23; 2009 = 26/26; 2010 = 36/36; 2011 = 32/32; 2012 = 23/23; 2013 = 18/18; 2014 = 23/23; 2015 = 37/37; 2016 = 54/54; 2017 = 34/34; 2018 = 38/38; 2019 = 32/32; 2020 = 42/42; 2021 = 34/34; 2022 = 22/22; 2023 = 38/39; 2024 = 20/38



**PMA Originals and Panel Track Supplements Without Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 3/31/2025**



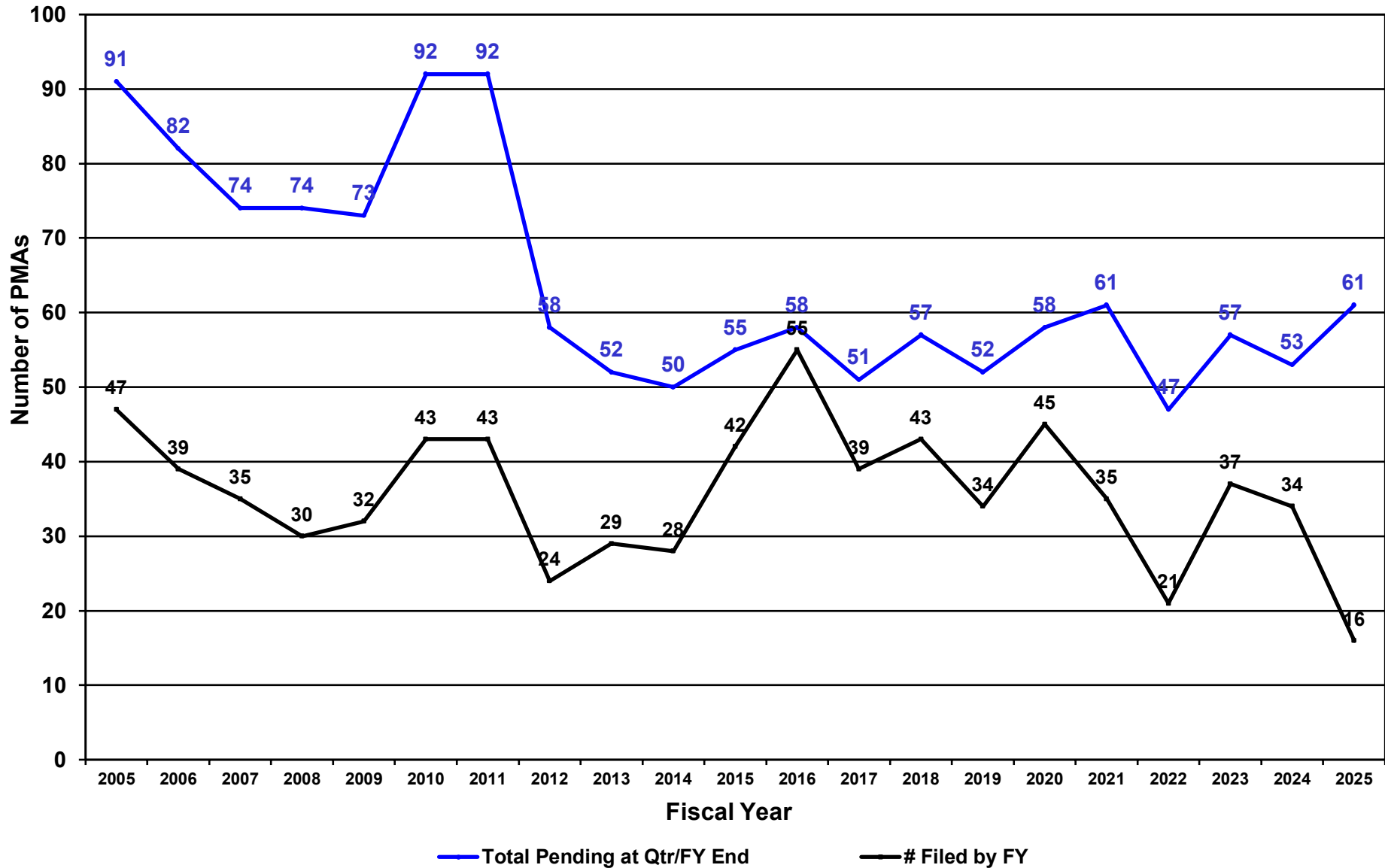
Numbers Closed/Filed: 2007 = 31/31; 2008 = 29/29; 2009 = 36/36; 2010 = 50/50; 2011 = 37/37; 2012 = 32/32; 2013 = 27/27; 2014 = 36/36; 2015 = 62/62; 2016 = 70/70; 2017 = 60/60; 2018 = 66/66; 2019 = 53/53; 2020 = 69/69; 2021 = 69/69; 2022 = 44/44; 2023 = 67/68; 2024 = 36/64

— Avg FDA Days to MDUFA Decision PMAO-PTS — Avg MFR Days to MDUFA Decision PMAO-PTS — Avg Total Days to MDUFA Decision PMAO-PTS

Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.



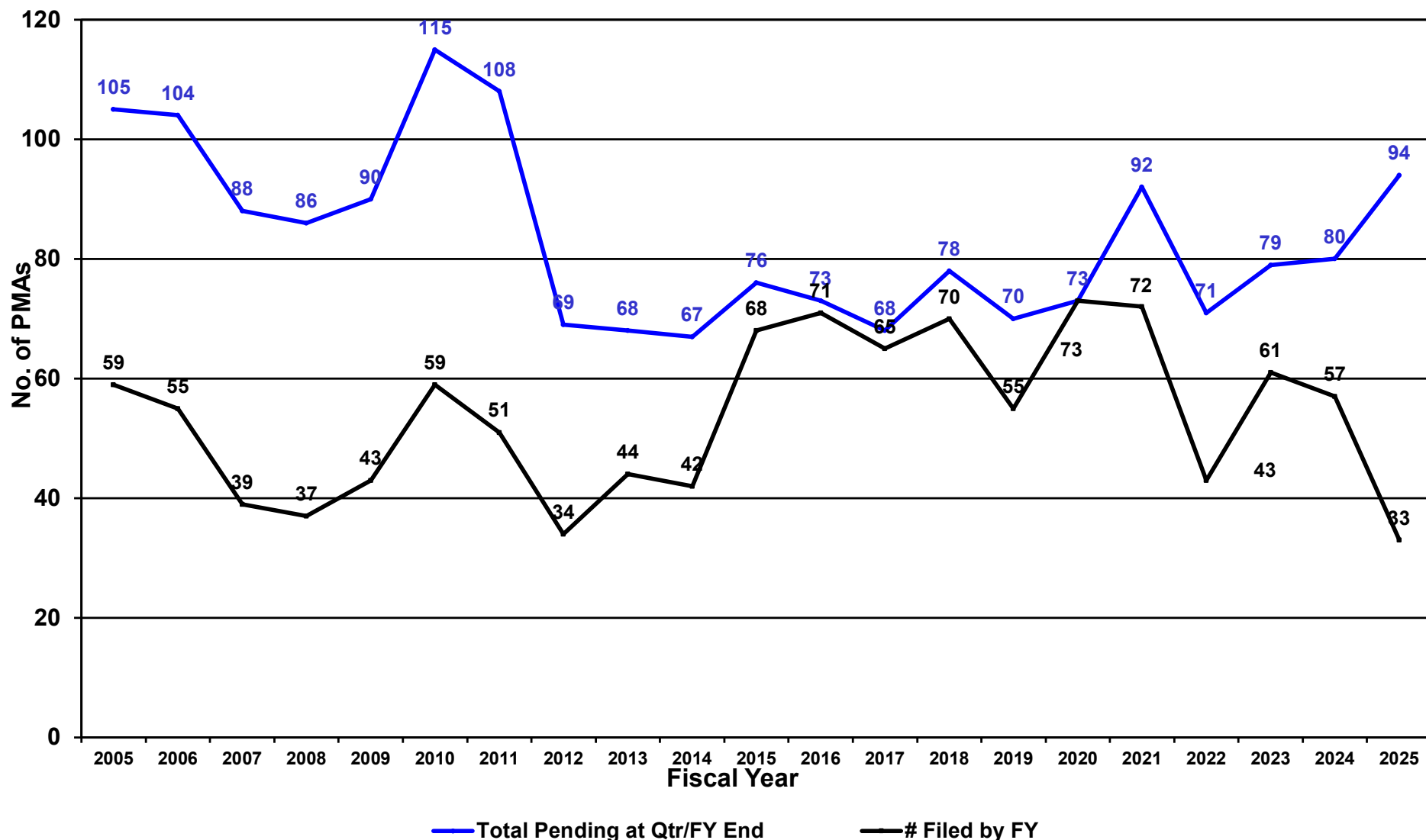
# PMA Originals Pending\* at End of Quarter/Year



\*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.



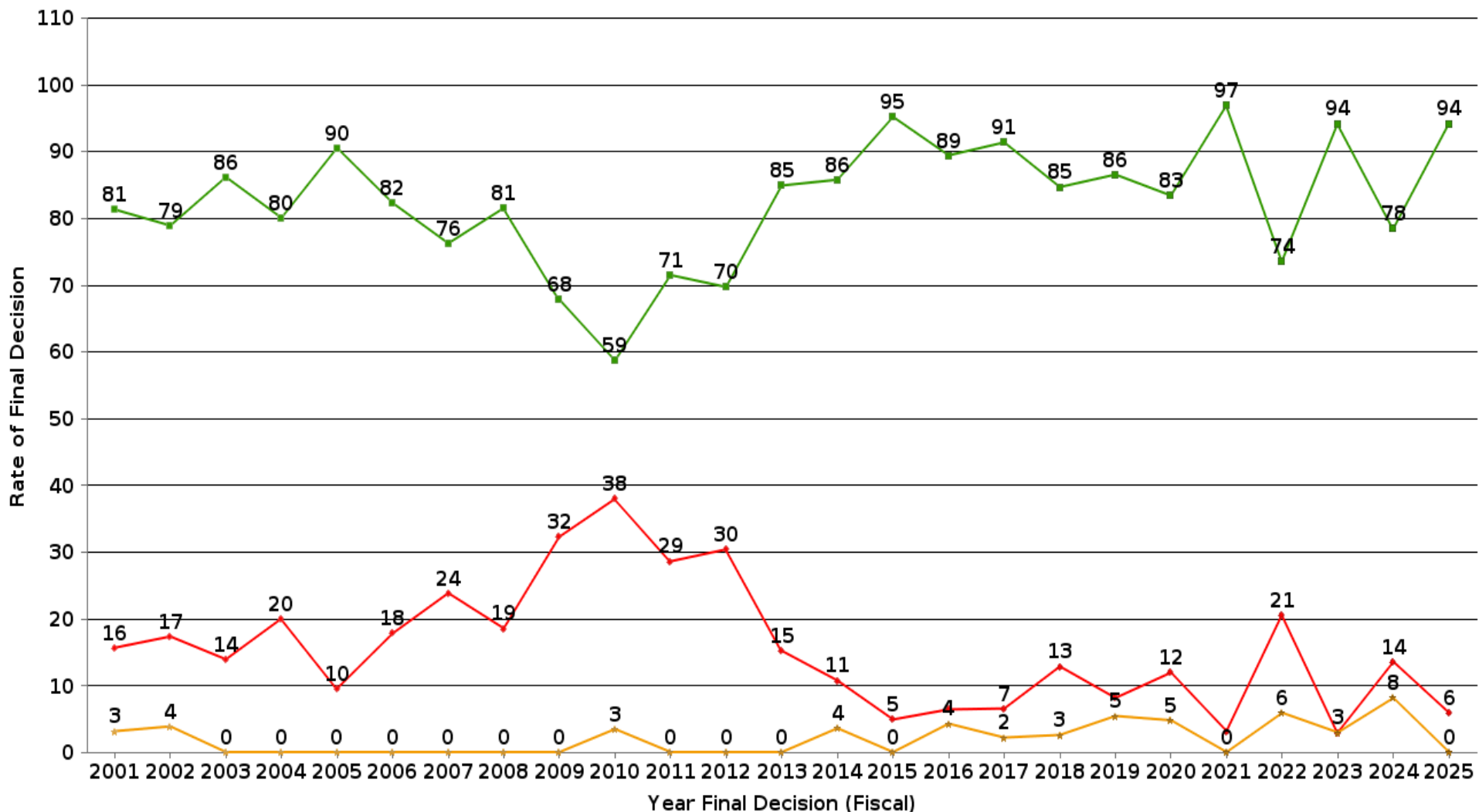
# PMA Originals and Panel Track Supplements Pending\* at End of Quarter/Year



\*Original PMAs/PTS awaiting filing, MDUFA or final decision, under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.



PMA Originals Rates of Approval, Withdrawal and Other Decisions by FY of Final Decision



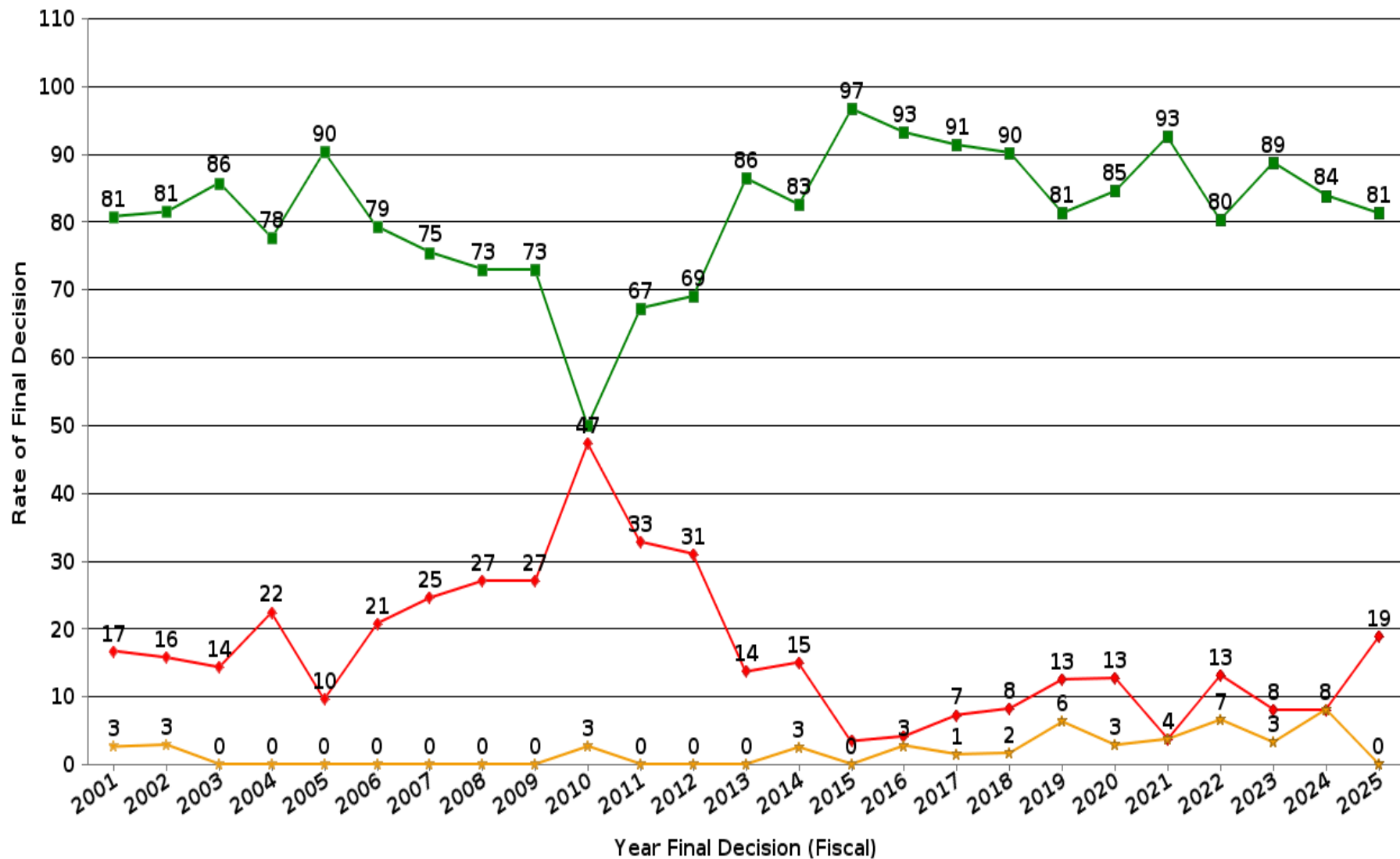
Current FY data represents a partial year in 1st, 2nd and 3rd quarter reporting.

■ % Approved PMAO ♦ % WTDR PMAO ★ % Other PMAO

Submissions deleted due to lack of response were counted as “withdrawals” prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as “withdrawals” from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered “other” decisions from FY16 onward



PMA Originals and Panel Track Supplements Rates of Approval, Withdrawal and Other Decisions by FY of Final Decision



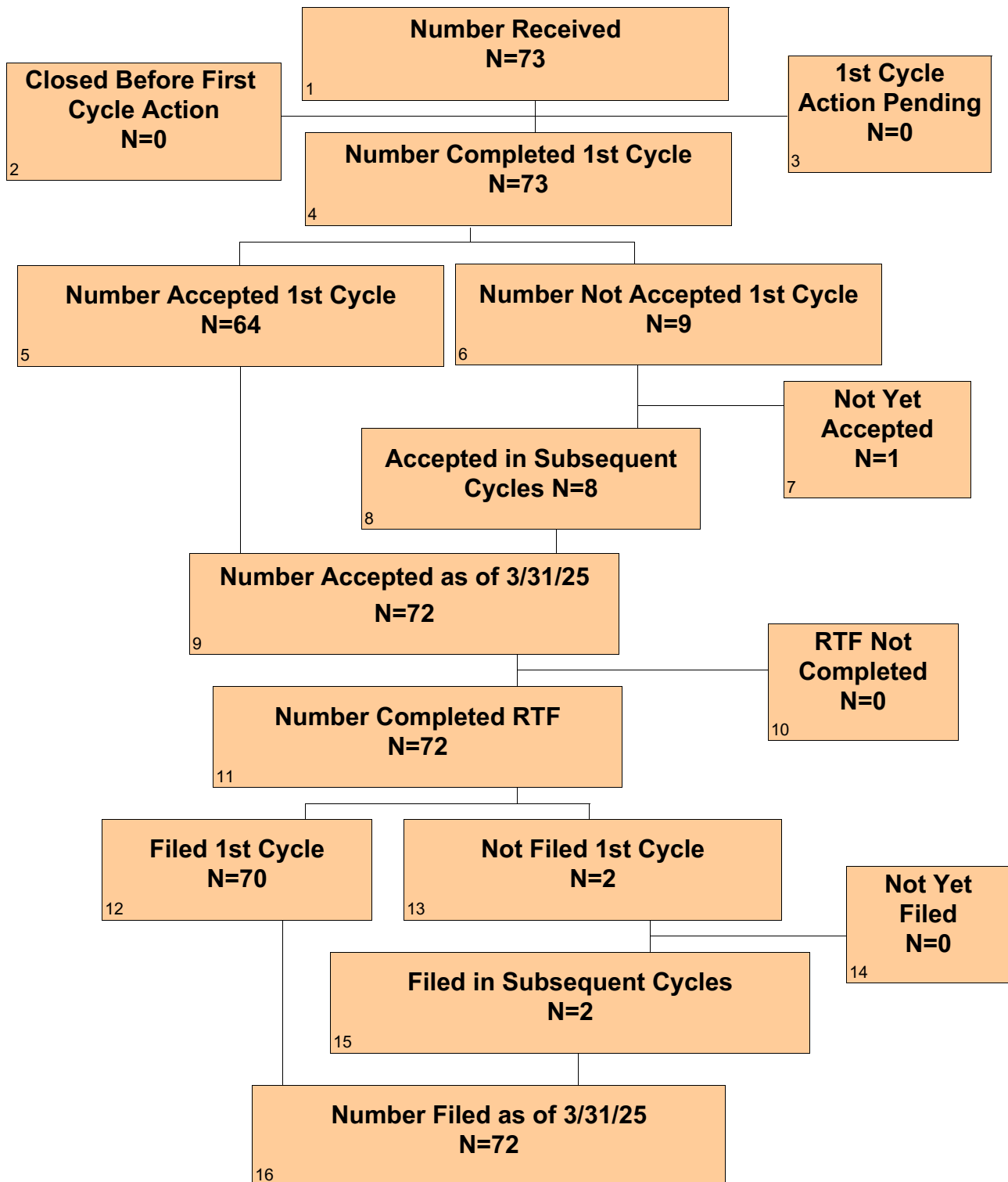
Current FY data represents a partial year in 1st, 2nd and 3rd quarter reporting.

■ % Approved PMAO-PTS ♦ % WTDR PMAO-PTS ★ % All Other PMAO-PTS

Submissions deleted due to lack of response were counted as “withdrawals” prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as “withdrawals” from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered “other” decisions from FY16 onward

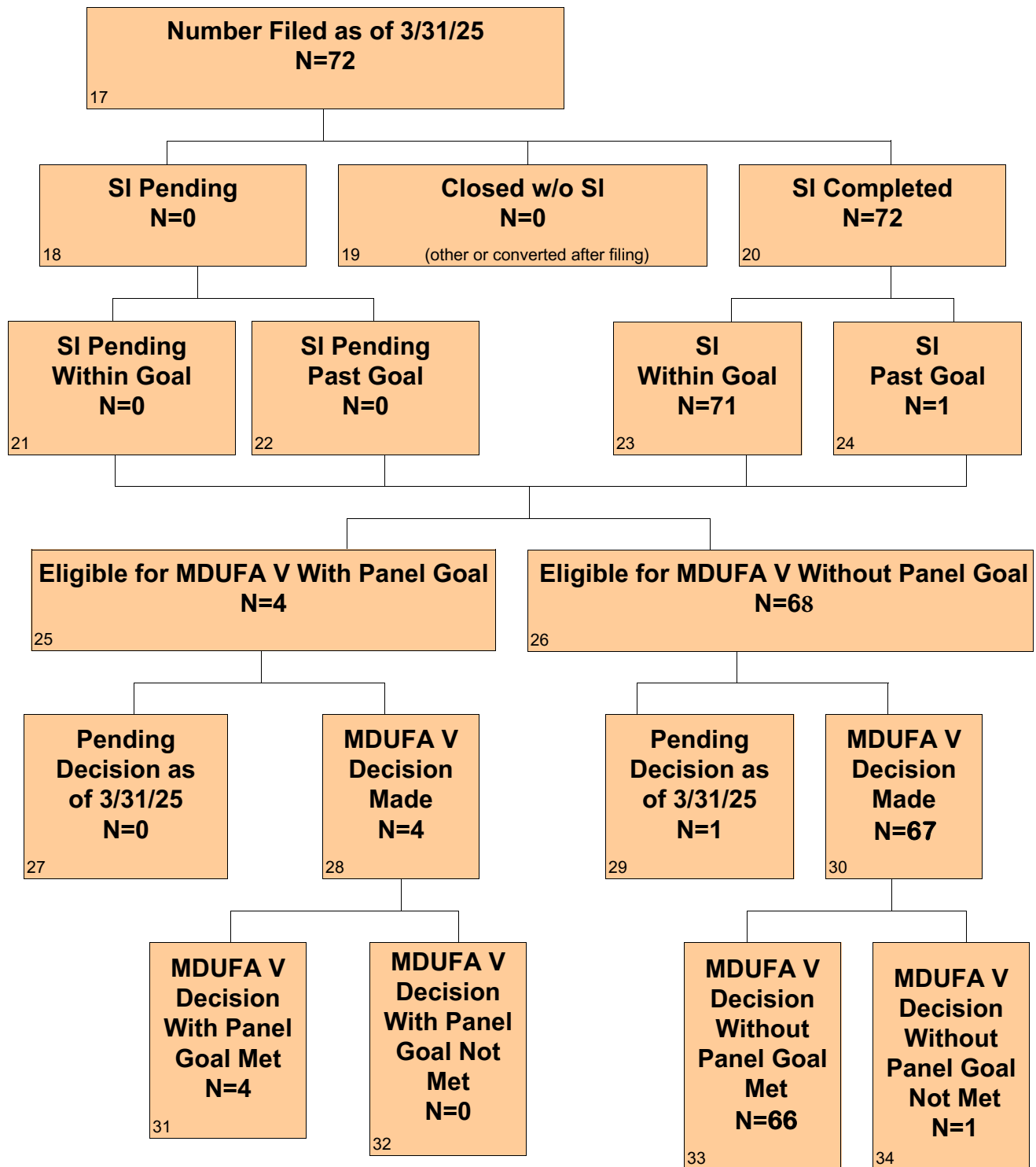


# CDRH PMA Original and Panel Track Supplements - FY 2023 as of 3/31/25



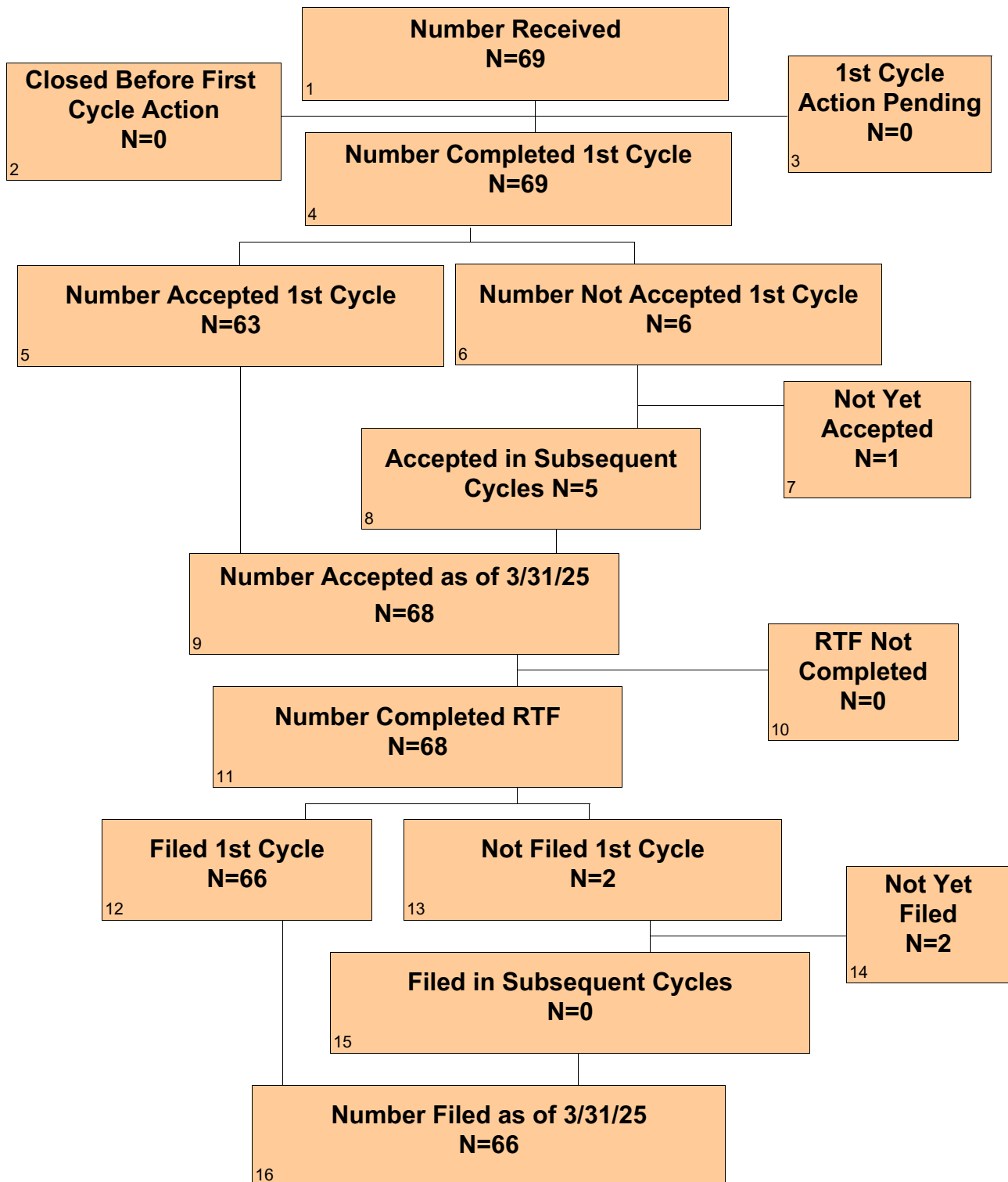


# CDRH PMA Original and Panel Track Supplements - FY 2023 as of 3/31/25 Con't



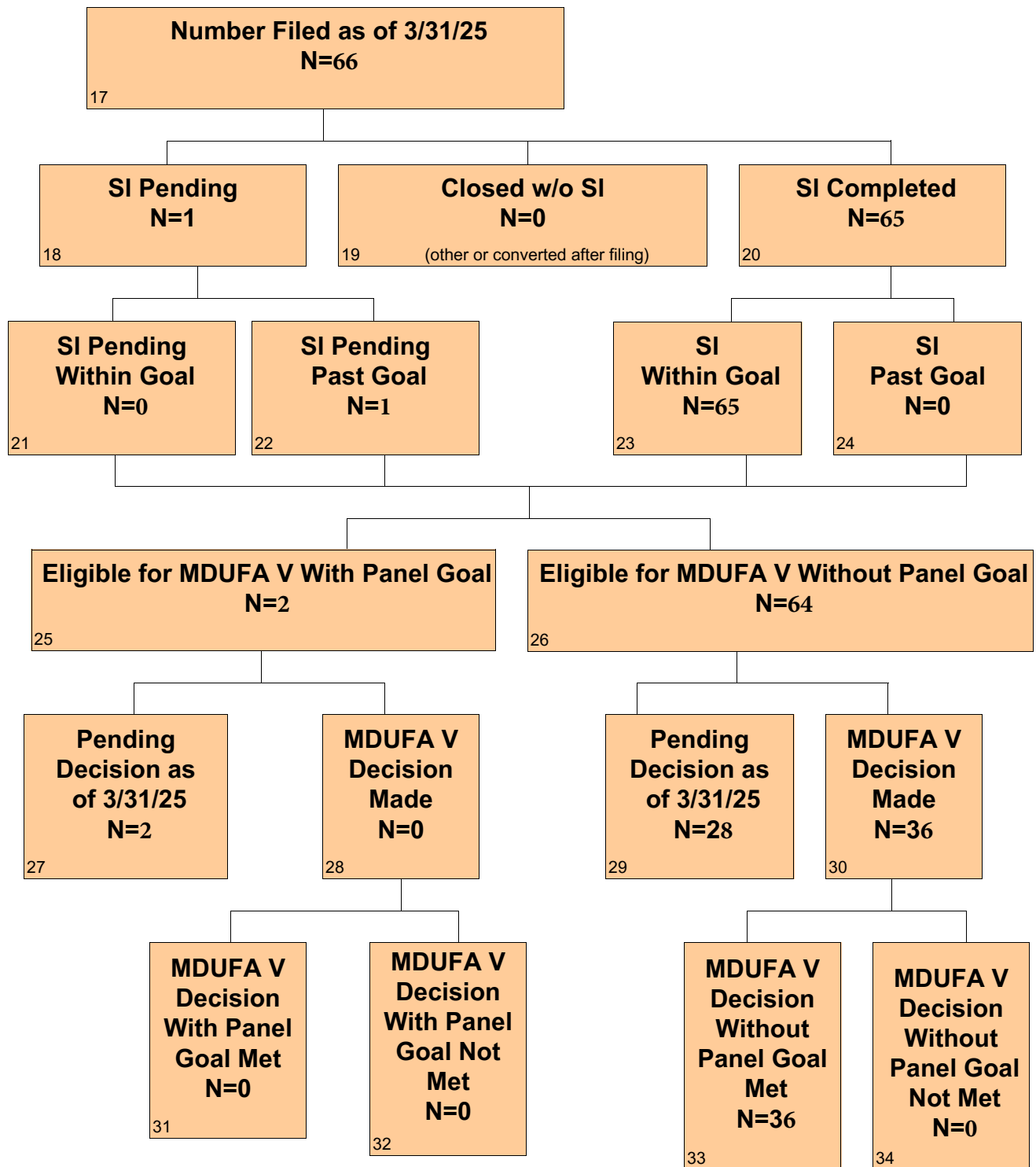


# CDRH PMA Original and Panel Track Supplements - FY 2024 as of 3/31/25



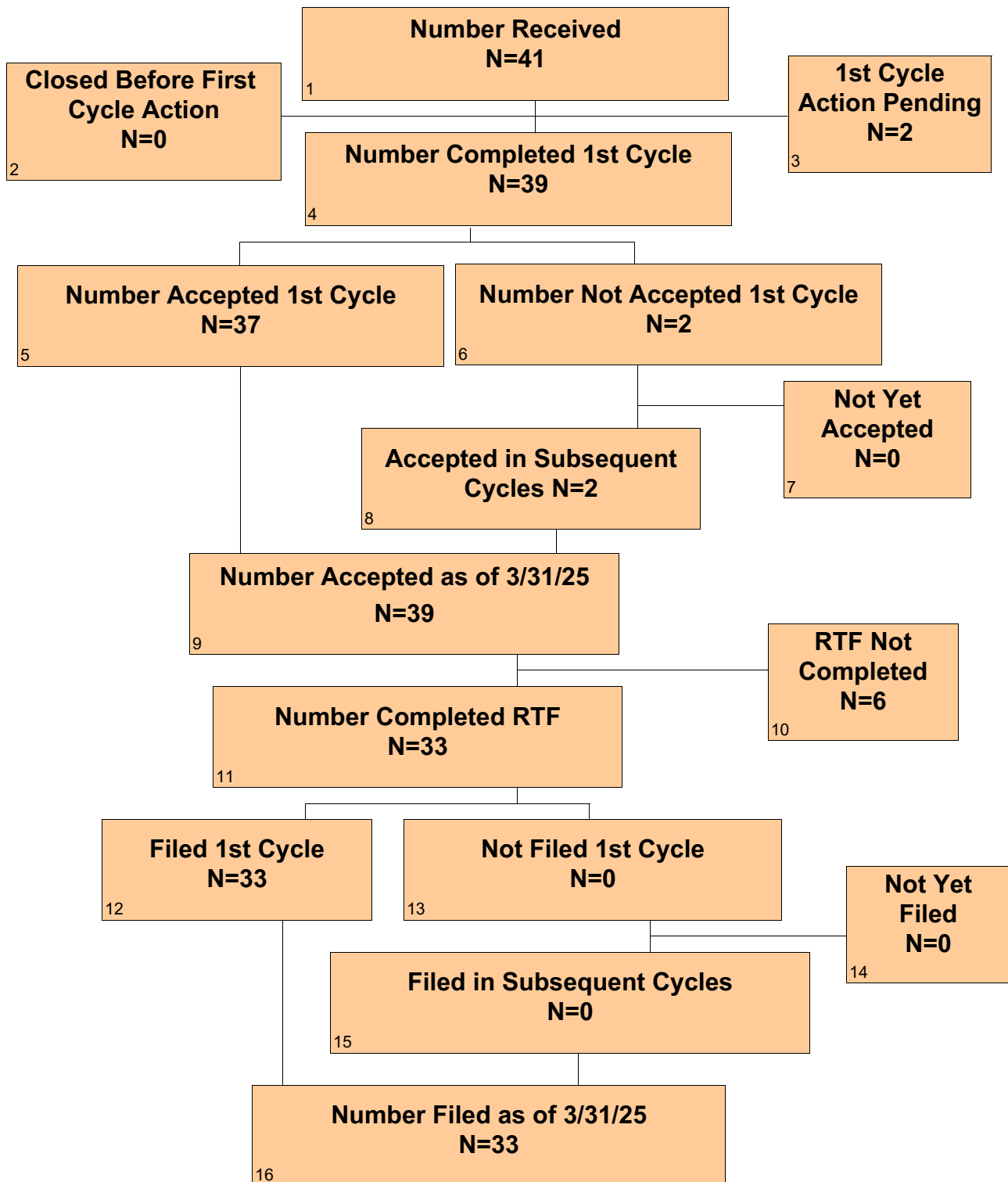


# CDRH PMA Original and Panel Track Supplements - FY 2024 as of 3/31/25 Con't



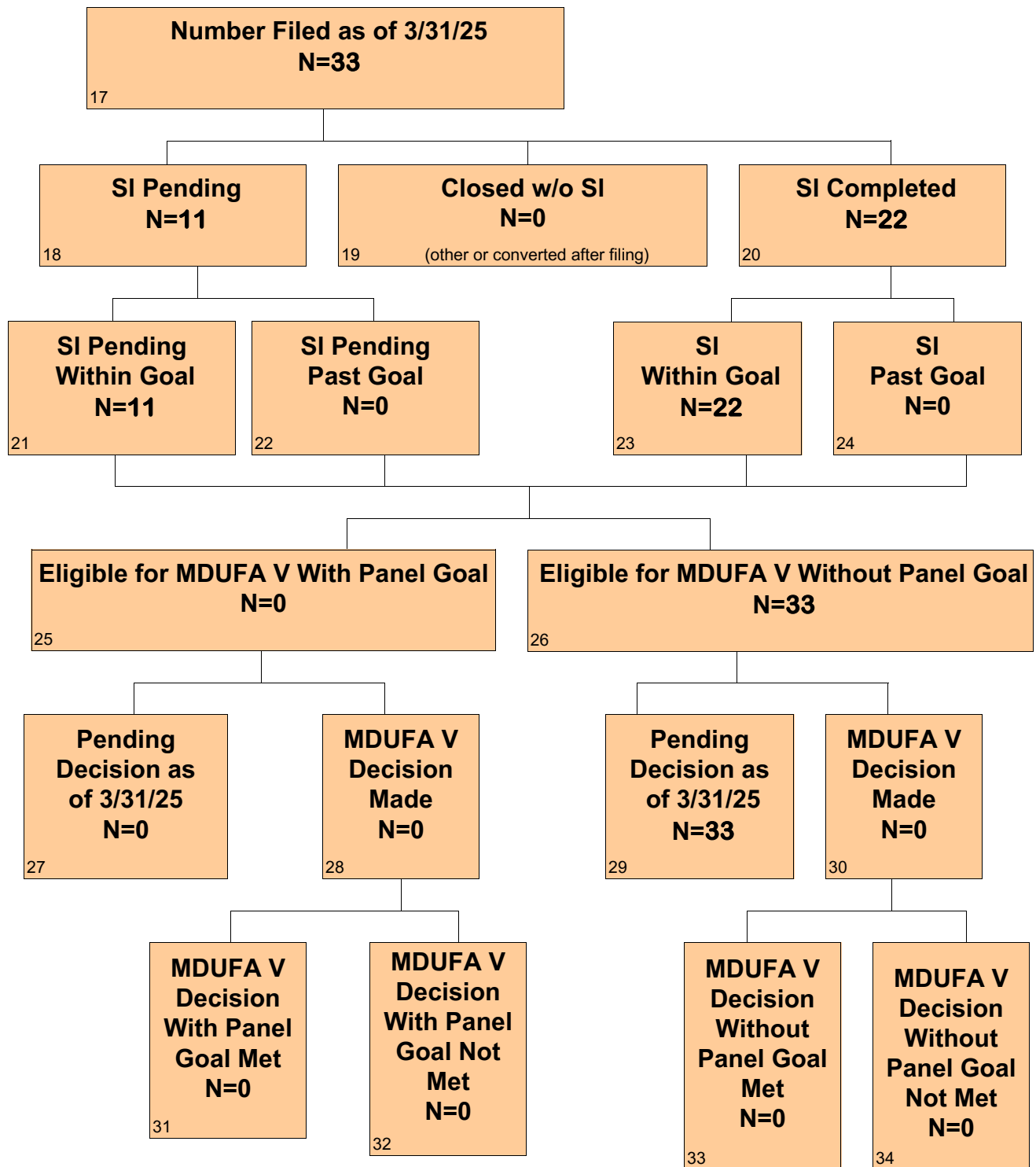


# CDRH PMA Original and Panel Track Supplements - FY 2025 as of 3/31/25





# CDRH PMA Original and Panel Track Supplements - FY 2025 as of 3/31/25 Con't





## Section 1 PMA Original and Panel-Track Supplements - Center Level Metric

**Table 1.1 CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	73	69	41		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	64	61	37		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	2	0		
Number Without a First RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	2		
Number Not Accepted for Filing Review on First Cycle	9	6	2		
Rate of Submissions Not Accepted for Filing Review on First Cycle	12.33%	8.70%	5.13%		

\*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

**Table 1.2 CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	73	69	41		
Number Accepted	64	63	37		
Completed RTF	72	68	33		
Number Not Filed	2	2	0		
Rate of Submissions Not Filed	2.78%	2.94%	0.00%		

**Table 1.3 CDRH - PMA Original and Panel-Track Supplements Substantive Interaction**

### Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	72	66	33		
SI Goal Met	71	65	22		
SI Goal Not Met	1	0	0		
SI Pending Within Goal	0	0	11		
SI Pending Past Goal	0	1	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	98.61%	98.48%	100.00%		



**Table 1.4 CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interactions	72	65	22		
Average Number of FDA Days to Substantive Interaction	87.42	88.14	83.68		
20th Percentile FDA Days to Substantive Interaction	86	88	86		
40th Percentile FDA Days to Substantive Interaction	88	89	88		
60th Percentile FDA Days to Substantive Interaction	90	90	89		
80th Percentile FDA Days to Substantive Interaction	90	90	90		
Maximum FDA Days to Substantive Interaction	91	90	90		

**Table 1.5 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 180 FDA Days	<b>FY 2024</b> 90% Within 180 FDA Days	<b>FY 2025</b> 90% Within 180 FDA Days	<b>FY 2026</b> 90% Within 180 FDA Days	<b>FY 2027</b> 90% Within 180 FDA Days
Number of PMAs Filed	68	64	33		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	67	36	0		
MDUFA Decision Goal Met	66	36	0		
PMAs Pending MDUFA Decision	1	28	33		
PMAs Pending MDUFA Decision Past Goal	0	1	0		
Current Performance Percent Goal Met	98.51%	97.30%	N/A		

**Table 1.6 CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 320 FDA Days	<b>FY 2024</b> 90% Within 320 FDA Days	<b>FY 2025</b> 90% Within 320 FDA Days	<b>FY 2026</b> 90% Within 320 FDA Days	<b>FY 2027</b> 90% Within 320 FDA Days
Number of PMAs Filed	4	2	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	4	0	0		
MDUFA Decision Goal Met	4	0	0		
PMAs Pending MDUFA Decision	0	2	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	N/A	N/A		



**Table 1.7 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)**  
**Performance Metric - Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	67	36	0		
<b>Average FDA Days to MDUFA Decision</b>	168.43	172.78	N/A		
20th Percentile FDA Days to MDUFA Decision	171	176	0		
40th Percentile FDA Days to MDUFA Decision	178	178	0		
60th Percentile FDA Days to MDUFA Decision	180	180	0		
80th Percentile FDA Days to MDUFA Decision	180	180	0		
Maximum FDA Days to MDUFA Decision	271	180	0		
<b>Average Industry Days to MDUFA Decision</b>	118.27	67.17	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	39	29	0		
60th Percentile Industry Days to MDUFA Decision	98	57	0		
80th Percentile Industry Days to MDUFA Decision	277	125	0		
Maximum Industry Days to MDUFA Decision	362	311	0		
<b>Average Total Days to MDUFA Decision</b>	286.70	239.94	N/A		
20th Percentile Total Days to MDUFA Decision	179	179	0		
40th Percentile Total Days to MDUFA Decision	218	198	0		
60th Percentile Total Days to MDUFA Decision	281	231	0		
80th Percentile Total Days to MDUFA Decision	444	305	0		
Maximum Total Days to MDUFA Decision	536	491	0		



**Table 1.8 CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	4	0	0		
<b>Average FDA Days to MDUFA Decision</b>	319.00	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	318	0	0		
40th Percentile FDA Days to MDUFA Decision	318	0	0		
60th Percentile FDA Days to MDUFA Decision	320	0	0		
80th Percentile FDA Days to MDUFA Decision	320	0	0		
Maximum FDA Days to MDUFA Decision	320	0	0		
<b>Average Industry Days to MDUFA Decision</b>	90.00	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	51	0	0		
40th Percentile Industry Days to MDUFA Decision	61	0	0		
60th Percentile Industry Days to MDUFA Decision	72	0	0		
80th Percentile Industry Days to MDUFA Decision	120	0	0		
Maximum Industry Days to MDUFA Decision	186	0	0		
<b>Average Total Days to MDUFA Decision</b>	409.00	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	370	0	0		
40th Percentile Total Days to MDUFA Decision	381	0	0		
60th Percentile Total Days to MDUFA Decision	392	0	0		
80th Percentile Total Days to MDUFA Decision	439	0	0		
Maximum Total Days to MDUFA Decision	504	0	0		



**Table 1.9 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	68	64	33		
Number with MDUFA Decision	67	36	0		
Number of Withdrawal	3	2	0		
Number of Not Approvable	12	5	0		
Number of Deleted	1	0	0		
Rate of Withdrawal	4.48%	5.56%	N/A		
Rate of Not Approvable	17.91%	13.89%	N/A		

**Table 1.10 CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	4	2	0		
Number With MDUFA Decision	4	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	N/A	N/A		
Rate of Not Approvable	0.00%	N/A	N/A		

**Table 1.11 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	1	0		
Mean FDA Days for Submissions that Missed the Goal	191.00	217.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	28.00	0.00	N/A		

**Table 1.12 CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		



**Table 1.13 CDRH - LDT PMA Original and Panel-Track Supplements MDUFA V Metric\***

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 180 FDA Days	<b>FY 2024</b> 90% Within 180 FDA Days	<b>FY 2025</b> 90% Within 180 FDA Days	<b>FY 2026</b> 90% Within 180 FDA Days	<b>FY 2027</b> 90% Within 180 FDA Days
Number of PMAs Filed	6	5	3		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	6	2	0		
MDUFA Decision Goal Met	6	2	0		
PMAs Pending MDUFA Decision	0	3	3		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

\*Includes submission that went to panel

**Table 1.14 CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric\***

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 320 FDA Days	<b>FY 2024</b> 90% Within 320 FDA Days	<b>FY 2025</b> 90% Within 320 FDA Days	<b>FY 2026</b> 90% Within 320 FDA Days	<b>FY 2027</b> 90% Within 320 FDA Days
Number of PMAs Filed	15	10	6		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	15	6	0		
MDUFA Decision Goal Met	15	6	0		
PMAs Pending MDUFA Decision	0	4	6		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

\*Includes submission that went to panel



## Section 1 PMA Original and Panel-Track Supplements - Office Level Metric

**Table 1.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device**

### PMA Original and Panel-Track Supplements - Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	7	5		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	3	6	5		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted for Filing Review on First Cycle	6	1	0		
Rate of Submissions Not Accepted for Filing Review on First Cycle	66.67%	14.29%	0.00%		

\*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

**Table 1.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device**

### PMA Original and Panel-Track Supplements - Filing Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	7	5		
Number Accepted	3	6	5		
Completed RTF	8	7	4		
Number Not Filed	1	0	0		
Rate of Submissions Not Filed	12.50%	0.00%	0.00%		

**Table 1.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device**

### PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	8	7	4		
SI Goal Met	8	7	2		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%		



**Table 1.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device**  
**PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interactions	8	7	2		
Average Number of FDA Days to Substantive Interaction	82.00	89.43	88.50		
20th Percentile FDA Days to Substantive Interaction	87	88	88		
40th Percentile FDA Days to Substantive Interaction	90	90	88		
60th Percentile FDA Days to Substantive Interaction	90	90	89		
80th Percentile FDA Days to Substantive Interaction	90	90	89		
Maximum FDA Days to Substantive Interaction	90	90	90		

**Table 1.5 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device**  
**PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 180 FDA Days	<b>FY 2024</b> 90% Within 180 FDA Days	<b>FY 2025</b> 90% Within 180 FDA Days	<b>FY 2026</b> 90% Within 180 FDA Days	<b>FY 2027</b> 90% Within 180 FDA Days
Number of PMAs Filed	8	7	4		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	8	7	0		
MDUFA Decision Goal Met	8	7	0		
PMAs Pending MDUFA Decision	0	0	4		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

**Table 1.6 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device**  
**PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 320 FDA Days	<b>FY 2024</b> 90% Within 320 FDA Days	<b>FY 2025</b> 90% Within 320 FDA Days	<b>FY 2026</b> 90% Within 320 FDA Days	<b>FY 2027</b> 90% Within 320 FDA Days
Number of PMAs Filed	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Goal Met	0	0	0		
PMAs Pending MDUFA Decision	0	0	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	N/A	N/A		



**Table 1.7 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V  
Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	8	7	0		
<b>Average FDA Days to MDUFA Decision</b>	138.00	180.00	N/A		
20th Percentile FDA Days to MDUFA Decision	90	180	0		
40th Percentile FDA Days to MDUFA Decision	157	180	0		
60th Percentile FDA Days to MDUFA Decision	179	180	0		
80th Percentile FDA Days to MDUFA Decision	180	180	0		
Maximum FDA Days to MDUFA Decision	180	180	0		
<b>Average Industry Days to MDUFA Decision</b>	217.75	145.43	N/A		
20th Percentile Industry Days to MDUFA Decision	65	65	0		
40th Percentile Industry Days to MDUFA Decision	247	102	0		
60th Percentile Industry Days to MDUFA Decision	295	148	0		
80th Percentile Industry Days to MDUFA Decision	337	236	0		
Maximum Industry Days to MDUFA Decision	362	311	0		
<b>Average Total Days to MDUFA Decision</b>	355.75	325.43	N/A		
20th Percentile Total Days to MDUFA Decision	245	245	0		
40th Percentile Total Days to MDUFA Decision	354	282	0		
60th Percentile Total Days to MDUFA Decision	456	328	0		
80th Percentile Total Days to MDUFA Decision	478	416	0		
Maximum Total Days to MDUFA Decision	536	491	0		



**Table 1.8 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V  
Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	0	0	0		
<b>Average FDA Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
<b>Average Industry Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
<b>Average Total Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	0	0	0		



**Table 1.9 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of  
Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	8	7	4		
Number with MDUFA Decision	8	7	0		
Number of Withdrawal	1	0	0		
Number of Not Approvable	0	1	0		
Number of Deleted	1	0	0		
Rate of Withdrawal	12.50%	0.00%	N/A		
Rate of Not Approvable	0.00%	14.29%	N/A		

**Table 1.10 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of  
Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0	0		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	N/A	N/A	N/A		

**Table 1.11 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions  
Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		

**Table 1.12 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing  
Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		



**Table 1.13 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
LDT PMA Original and Panel-Track Supplements MDUFA V Metric\***

<b>Performance Metric</b>	<b>FY 2023 90% Within 180 FDA Days</b>	<b>FY 2024 90% Within 180 FDA Days</b>	<b>FY 2025 90% Within 180 FDA Days</b>	<b>FY 2026 90% Within 180 FDA Days</b>	<b>FY 2027 90% Within 180 FDA Days</b>
Number of PMAs Filed	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

\*Includes submission that went to panel

**Table 1.14 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric\***

<b>Performance Metric</b>	<b>FY 2023 90% Within 320 FDA Days</b>	<b>FY 2024 90% Within 320 FDA Days</b>	<b>FY 2025 90% Within 320 FDA Days</b>	<b>FY 2026 90% Within 320 FDA Days</b>	<b>FY 2027 90% Within 320 FDA Days</b>
Number of PMAs Filed	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

\*Includes submission that went to panel



**Table 1.1 OHT2 - Office of Cardiovascular Devices****PMA Original and Panel-Track Supplements - Acceptance Review Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	20	20	14		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	19	17	13		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	2	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted for Filing Review on First Cycle	1	1	1		
Rate of Submissions Not Accepted for Filing Review on First Cycle	5.00%	5.00%	7.14%		

\*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

**Table 1.2 OHT2 - Office of Cardiovascular Devices****PMA Original and Panel-Track Supplements - Filing Review Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	20	20	14		
Number Accepted	19	19	13		
Completed RTF	20	20	12		
Number Not Filed	0	1	0		
Rate of Submissions Not Filed	0.00%	5.00%	0.00%		

**Table 1.3 OHT2 - Office of Cardiovascular Devices****PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

<b>Substantive Interaction (SI) Goal</b>	<b>FY 2023 95% SI Within 90 FDA Days</b>	<b>FY 2024 95% SI Within 90 FDA Days</b>	<b>FY 2025 95% SI Within 90 FDA Days</b>	<b>FY 2026 95% SI Within 90 FDA Days</b>	<b>FY 2027 95% SI Within 90 FDA Days</b>
Eligible for SI	20	19	12		
SI Goal Met	20	19	9		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	3		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%		



**Table 1.4 OHT2 - Office of Cardiovascular Devices****PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interactions	20	19	9		
Average Number of FDA Days to Substantive Interaction	88.25	88.11	87.56		
20th Percentile FDA Days to Substantive Interaction	86	87	88		
40th Percentile FDA Days to Substantive Interaction	90	88	89		
60th Percentile FDA Days to Substantive Interaction	90	90	90		
80th Percentile FDA Days to Substantive Interaction	90	90	90		
Maximum FDA Days to Substantive Interaction	90	90	90		

**Table 1.5 OHT2 - Office of Cardiovascular Devices****PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 90% Within 180 FDA Days</b>	<b>FY 2024 90% Within 180 FDA Days</b>	<b>FY 2025 90% Within 180 FDA Days</b>	<b>FY 2026 90% Within 180 FDA Days</b>	<b>FY 2027 90% Within 180 FDA Days</b>
Number of PMAs Filed	17	18	12		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	17	12	0		
MDUFA Decision Goal Met	17	12	0		
PMAs Pending MDUFA Decision	0	6	12		
PMAs Pending MDUFA Decision Past Goal	0	1	0		
Current Performance Percent Goal Met	100.00%	92.31%	N/A		

**Table 1.6 OHT2 - Office of Cardiovascular Devices****PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 90% Within 320 FDA Days</b>	<b>FY 2024 90% Within 320 FDA Days</b>	<b>FY 2025 90% Within 320 FDA Days</b>	<b>FY 2026 90% Within 320 FDA Days</b>	<b>FY 2027 90% Within 320 FDA Days</b>
Number of PMAs Filed	3	1	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	3	0	0		
MDUFA Decision Goal Met	3	0	0		
PMAs Pending MDUFA Decision	0	1	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	#DIV/0!	#DIV/0!		



**Table 1.7 OHT2 - Office of Cardiovascular Devices**

**PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	17	12	0		
<b>Average FDA Days to MDUFA Decision</b>	177.65	175.17	N/A		
20th Percentile FDA Days to MDUFA Decision	172	176	0		
40th Percentile FDA Days to MDUFA Decision	177	178	0		
60th Percentile FDA Days to MDUFA Decision	180	180	0		
80th Percentile FDA Days to MDUFA Decision	180	180	0		
Maximum FDA Days to MDUFA Decision	271	180	0		
<b>Average Industry Days to MDUFA Decision</b>	64.29	11.58	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	23	0	0		
60th Percentile Industry Days to MDUFA Decision	47	6	0		
80th Percentile Industry Days to MDUFA Decision	113	27	0		
Maximum Industry Days to MDUFA Decision	271	51	0		
<b>Average Total Days to MDUFA Decision</b>	241.94	186.75	N/A		
20th Percentile Total Days to MDUFA Decision	176	178	0		
40th Percentile Total Days to MDUFA Decision	201	179	0		
60th Percentile Total Days to MDUFA Decision	236	186	0		
80th Percentile Total Days to MDUFA Decision	305	196	0		
Maximum Total Days to MDUFA Decision	442	231	0		



**Table 1.8 OHT2 - Office of Cardiovascular Devices**

**PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	3	0	0		
<b>Average FDA Days to MDUFA Decision</b>	319.33	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	319	0	0		
40th Percentile FDA Days to MDUFA Decision	320	0	0		
60th Percentile FDA Days to MDUFA Decision	320	0	0		
80th Percentile FDA Days to MDUFA Decision	320	0	0		
Maximum FDA Days to MDUFA Decision	320	0	0		
<b>Average Industry Days to MDUFA Decision</b>	58.00	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	47	0	0		
40th Percentile Industry Days to MDUFA Decision	54	0	0		
60th Percentile Industry Days to MDUFA Decision	61	0	0		
80th Percentile Industry Days to MDUFA Decision	68	0	0		
Maximum Industry Days to MDUFA Decision	76	0	0		
<b>Average Total Days to MDUFA Decision</b>	377.33	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	366	0	0		
40th Percentile Total Days to MDUFA Decision	373	0	0		
60th Percentile Total Days to MDUFA Decision	381	0	0		
80th Percentile Total Days to MDUFA Decision	388	0	0		
Maximum Total Days to MDUFA Decision	396	0	0		



**Table 1.9 OHT2 - Office of Cardiovascular Devices****PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	17	18	12		
Number with MDUFA Decision	17	12	0		
Number of Withdrawal	1	0	0		
Number of Not Approvable	3	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	5.88%	0.00%	N/A		
Rate of Not Approvable	17.65%	0.00%	N/A		

**Table 1.10 OHT2 - Office of Cardiovascular Devices****PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	3	1	0		
Number With MDUFA Decision	3	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	N/A	N/A		
Rate of Not Approvable	0.00%	N/A	N/A		

**Table 1.11 OHT2 - Office of Cardiovascular Devices****PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	1	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	217.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	0.00	N/A		

**Table 1.12 OHT2 - Office of Cardiovascular Devices****PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		



**Table 1.13 OHT2 - Office of Cardiovascular Devices**  
**LDT PMA Original and Panel-Track Supplements MDUFA V Metric\***

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 180 FDA Days	<b>FY 2024</b> 90% Within 180 FDA Days	<b>FY 2025</b> 90% Within 180 FDA Days	<b>FY 2026</b> 90% Within 180 FDA Days	<b>FY 2027</b> 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

\*Includes submission that went to panel

**Table 1.14 OHT2 - Office of Cardiovascular Devices**  
**Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric\***

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 320 FDA Days	<b>FY 2024</b> 90% Within 320 FDA Days	<b>FY 2025</b> 90% Within 320 FDA Days	<b>FY 2026</b> 90% Within 320 FDA Days	<b>FY 2027</b> 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

\*Includes submission that went to panel



**Table 1.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	7	1		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	3	6	1		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted for Filing Review on First Cycle	0	1	0		
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	14.29%	0.00%		

\*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

**Table 1.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	7	1		
Number Accepted	3	6	1		
Completed RTF	3	7	0		
Number Not Filed	0	1	0		
Rate of Submissions Not Filed	0.00%	14.29%	#DIV/0!		

**Table 1.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	3	6	0		
SI Goal Met	3	5	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	1	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	83.33%	#DIV/0!		



**Table 1.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**

**PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interactions	3	5	0		
Average Number of FDA Days to Substantive Interaction	88.33	85.40	N/A		
20th Percentile FDA Days to Substantive Interaction	87	85	0		
40th Percentile FDA Days to Substantive Interaction	88	88	0		
60th Percentile FDA Days to Substantive Interaction	88	89	0		
80th Percentile FDA Days to Substantive Interaction	89	90	0		
Maximum FDA Days to Substantive Interaction	90	90	0		

**Table 1.5 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**

**PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 90% Within 180 FDA Days</b>	<b>FY 2024 90% Within 180 FDA Days</b>	<b>FY 2025 90% Within 180 FDA Days</b>	<b>FY 2026 90% Within 180 FDA Days</b>	<b>FY 2027 90% Within 180 FDA Days</b>
Number of PMAs Filed	3	6	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	3	1	0		
MDUFA Decision Goal Met	2	1	0		
PMAs Pending MDUFA Decision	0	5	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	66.67%	100.00%	#DIV/0!		

**Table 1.6 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**

**PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 90% Within 320 FDA Days</b>	<b>FY 2024 90% Within 320 FDA Days</b>	<b>FY 2025 90% Within 320 FDA Days</b>	<b>FY 2026 90% Within 320 FDA Days</b>	<b>FY 2027 90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Goal Met	0	0	0		
PMAs Pending MDUFA Decision	0	0	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	#DIV/0!	#DIV/0!	#DIV/0!		



**Table 1.7 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V  
Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	3	1	0		
<b>Average FDA Days to MDUFA Decision</b>	180.67	169.00	N/A		
20th Percentile FDA Days to MDUFA Decision	175	169	0		
40th Percentile FDA Days to MDUFA Decision	178	169	0		
60th Percentile FDA Days to MDUFA Decision	181	169	0		
80th Percentile FDA Days to MDUFA Decision	186	169	0		
Maximum FDA Days to MDUFA Decision	191	169	0		
<b>Average Industry Days to MDUFA Decision</b>	18.67	189.00	N/A		
20th Percentile Industry Days to MDUFA Decision	11	189	0		
40th Percentile Industry Days to MDUFA Decision	22	189	0		
60th Percentile Industry Days to MDUFA Decision	28	189	0		
80th Percentile Industry Days to MDUFA Decision	28	189	0		
Maximum Industry Days to MDUFA Decision	28	189	0		
<b>Average Total Days to MDUFA Decision</b>	199.33	358.00	N/A		
20th Percentile Total Days to MDUFA Decision	187	358	0		
40th Percentile Total Days to MDUFA Decision	196	358	0		
60th Percentile Total Days to MDUFA Decision	204	358	0		
80th Percentile Total Days to MDUFA Decision	211	358	0		
Maximum Total Days to MDUFA Decision	219	358	0		



**Table 1.8 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V  
Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	0	0	0		
<b>Average FDA Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
<b>Average Industry Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
<b>Average Total Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	0	0	0		



**Table 1.9 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	3	6	0		
Number with MDUFA Decision	3	1	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	1	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	0.00%	N/A		
Rate of Not Approvable	33.33%	0.00%	N/A		

**Table 1.10 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0	0		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	N/A	N/A	N/A		

**Table 1.11 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	0	0		
Mean FDA Days for Submissions that Missed the Goal	191.00	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	28.00	N/A	N/A		

**Table 1.12 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		



**Table 1.13 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**LDT PMA Original and Panel-Track Supplements MDUFA V Metric\***

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 180 FDA Days	<b>FY 2024</b> 90% Within 180 FDA Days	<b>FY 2025</b> 90% Within 180 FDA Days	<b>FY 2026</b> 90% Within 180 FDA Days	<b>FY 2027</b> 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

\*Includes submission that went to panel

**Table 1.14 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric\***

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 320 FDA Days	<b>FY 2024</b> 90% Within 320 FDA Days	<b>FY 2025</b> 90% Within 320 FDA Days	<b>FY 2026</b> 90% Within 320 FDA Days	<b>FY 2027</b> 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

\*Includes submission that went to panel



**Table 1.1 OHT4 - Office of Surgical and Infection Control Devices**  
**PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	6	4		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	9	6	3		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted for Filing Review on First Cycle	0	0	1		
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	0.00%	25.00%		

\*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

**Table 1.2 OHT4 - Office of Surgical and Infection Control Devices**  
**PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	6	4		
Number Accepted	9	6	3		
Completed RTF	9	6	3		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	0.00%	0.00%	0.00%		

**Table 1.3 OHT4 - Office of Surgical and Infection Control Devices**  
**PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	9	6	3		
SI Goal Met	9	6	2		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%		



**Table 1.4 OHT4 - Office of Surgical and Infection Control Devices****PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interactions	9	6	2		
Average Number of FDA Days to Substantive Interaction	88.78	89.33	87.00		
20th Percentile FDA Days to Substantive Interaction	88	89	86		
40th Percentile FDA Days to Substantive Interaction	90	89	87		
60th Percentile FDA Days to Substantive Interaction	90	90	87		
80th Percentile FDA Days to Substantive Interaction	90	90	88		
Maximum FDA Days to Substantive Interaction	90	90	88		

**Table 1.5 OHT4 - Office of Surgical and Infection Control Devices****PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 90% Within 180 FDA Days</b>	<b>FY 2024 90% Within 180 FDA Days</b>	<b>FY 2025 90% Within 180 FDA Days</b>	<b>FY 2026 90% Within 180 FDA Days</b>	<b>FY 2027 90% Within 180 FDA Days</b>
Number of PMAs Filed	9	5	3		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	8	1	0		
MDUFA Decision Goal Met	8	1	0		
PMAs Pending MDUFA Decision	1	4	3		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

**Table 1.6 OHT4 - Office of Surgical and Infection Control Devices****PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 90% Within 320 FDA Days</b>	<b>FY 2024 90% Within 320 FDA Days</b>	<b>FY 2025 90% Within 320 FDA Days</b>	<b>FY 2026 90% Within 320 FDA Days</b>	<b>FY 2027 90% Within 320 FDA Days</b>
Number of PMAs Filed	0	1	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Goal Met	0	0	0		
PMAs Pending MDUFA Decision	0	1	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	N/A	N/A		



**Table 1.7 OHT4 - Office of Surgical and Infection Control Devices**  
**PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	8	1	0		
<b>Average FDA Days to MDUFA Decision</b>	179.00	180.00	N/A		
20th Percentile FDA Days to MDUFA Decision	178	180	0		
40th Percentile FDA Days to MDUFA Decision	179	180	0		
60th Percentile FDA Days to MDUFA Decision	180	180	0		
80th Percentile FDA Days to MDUFA Decision	180	180	0		
Maximum FDA Days to MDUFA Decision	180	180	0		
<b>Average Industry Days to MDUFA Decision</b>	60.38	57.00	N/A		
20th Percentile Industry Days to MDUFA Decision	0	57	0		
40th Percentile Industry Days to MDUFA Decision	32	57	0		
60th Percentile Industry Days to MDUFA Decision	53	57	0		
80th Percentile Industry Days to MDUFA Decision	64	57	0		
Maximum Industry Days to MDUFA Decision	264	57	0		
<b>Average Total Days to MDUFA Decision</b>	239.38	237.00	N/A		
20th Percentile Total Days to MDUFA Decision	179	237	0		
40th Percentile Total Days to MDUFA Decision	210	237	0		
60th Percentile Total Days to MDUFA Decision	233	237	0		
80th Percentile Total Days to MDUFA Decision	244	237	0		
Maximum Total Days to MDUFA Decision	444	237	0		



**Table 1.8 OHT4 - Office of Surgical and Infection Control Devices**  
**PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	0	0	0		
<b>Average FDA Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
<b>Average Industry Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
<b>Average Total Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	0	0	0		



**Table 1.9 OHT4 - Office of Surgical and Infection Control Devices****PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	9	5	3		
Number with MDUFA Decision	8	1	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	1	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	0.00%	N/A		
Rate of Not Approvable	12.50%	0.00%	N/A		

**Table 1.10 OHT4 - Office of Surgical and Infection Control Devices****PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	1	0		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	N/A	N/A	N/A		

**Table 1.11 OHT4 - Office of Surgical and Infection Control Devices****PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		

**Table 1.12 OHT4 - Office of Surgical and Infection Control Devices****PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		



**Table 1.13 OHT4 - Office of Surgical and Infection Control Devices**  
**LDT PMA Original and Panel-Track Supplements MDUFA V Metric\***

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 180 FDA Days	<b>FY 2024</b> 90% Within 180 FDA Days	<b>FY 2025</b> 90% Within 180 FDA Days	<b>FY 2026</b> 90% Within 180 FDA Days	<b>FY 2027</b> 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

\*Includes submission that went to panel

**Table 1.14 OHT4 - Office of Surgical and Infection Control Devices**  
**Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric\***

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 320 FDA Days	<b>FY 2024</b> 90% Within 320 FDA Days	<b>FY 2025</b> 90% Within 320 FDA Days	<b>FY 2026</b> 90% Within 320 FDA Days	<b>FY 2027</b> 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

\*Includes submission that went to panel



**Table 1.1 OHT5 - Office of Neurological and Physical Medicine Devices  
PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	6	7	5		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	5	6	3		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	2		
Number Not Accepted for Filing Review on First Cycle	1	1	0		
Rate of Submissions Not Accepted for Filing Review on First Cycle	16.67%	14.29%	0.00%		

\*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

**Table 1.2 OHT5 - Office of Neurological and Physical Medicine Devices  
PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	6	7	5		
Number Accepted	5	6	3		
Completed RTF	6	7	3		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	0.00%	0.00%	0.00%		

**Table 1.3 OHT5 - Office of Neurological and Physical Medicine Devices  
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	6	7	3		
SI Goal Met	5	7	2		
SI Goal Not Met	1	0	0		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	83.33%	100.00%	100.00%		



**Table 1.4 OHT5 - Office of Neurological and Physical Medicine Devices PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interactions	6	7	2		
Average Number of FDA Days to Substantive Interaction	88.50	86.43	89.00		
20th Percentile FDA Days to Substantive Interaction	88	86	88		
40th Percentile FDA Days to Substantive Interaction	90	89	89		
60th Percentile FDA Days to Substantive Interaction	90	90	89		
80th Percentile FDA Days to Substantive Interaction	90	90	90		
Maximum FDA Days to Substantive Interaction	91	90	90		

**Table 1.5 OHT5 - Office of Neurological and Physical Medicine Devices PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 90% Within 180 FDA Days</b>	<b>FY 2024 90% Within 180 FDA Days</b>	<b>FY 2025 90% Within 180 FDA Days</b>	<b>FY 2026 90% Within 180 FDA Days</b>	<b>FY 2027 90% Within 180 FDA Days</b>
Number of PMAs Filed	6	7	3		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	6	5	0		
MDUFA Decision Goal Met	6	5	0		
PMAs Pending MDUFA Decision	0	2	3		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

**Table 1.6 OHT5 - Office of Neurological and Physical Medicine Devices PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 90% Within 320 FDA Days</b>	<b>FY 2024 90% Within 320 FDA Days</b>	<b>FY 2025 90% Within 320 FDA Days</b>	<b>FY 2026 90% Within 320 FDA Days</b>	<b>FY 2027 90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Goal Met	0	0	0		
PMAs Pending MDUFA Decision	0	0	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	N/A	N/A		



**Table 1.7 OHT5 - Office of Neurological and Physical Medicine Devices**  
**PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	6	5	0		
<b>Average FDA Days to MDUFA Decision</b>	175.33	159.40	N/A		
20th Percentile FDA Days to MDUFA Decision	179	158	0		
40th Percentile FDA Days to MDUFA Decision	180	177	0		
60th Percentile FDA Days to MDUFA Decision	180	177	0		
80th Percentile FDA Days to MDUFA Decision	180	178	0		
Maximum FDA Days to MDUFA Decision	180	178	0		
<b>Average Industry Days to MDUFA Decision</b>	55.17	92.00	N/A		
20th Percentile Industry Days to MDUFA Decision	0	29	0		
40th Percentile Industry Days to MDUFA Decision	37	57	0		
60th Percentile Industry Days to MDUFA Decision	71	84	0		
80th Percentile Industry Days to MDUFA Decision	101	133	0		
Maximum Industry Days to MDUFA Decision	122	249	0		
<b>Average Total Days to MDUFA Decision</b>	230.50	251.40	N/A		
20th Percentile Total Days to MDUFA Decision	180	207	0		
40th Percentile Total Days to MDUFA Decision	217	234	0		
60th Percentile Total Days to MDUFA Decision	251	261	0		
80th Percentile Total Days to MDUFA Decision	281	291	0		
Maximum Total Days to MDUFA Decision	301	337	0		



**Table 1.8 OHT5 - Office of Neurological and Physical Medicine Devices**  
**PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V**  
**Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	0	0	0		
<b>Average FDA Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
<b>Average Industry Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
<b>Average Total Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	0	0	0		



**Table 1.9 OHT5 - Office of Neurological and Physical Medicine Devices****PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	6	7	3		
Number with MDUFA Decision	6	5	0		
Number of Withdrawal	0	1	0		
Number of Not Approvable	1	2	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	20.00%	N/A		
Rate of Not Approvable	16.67%	40.00%	N/A		

**Table 1.10 OHT5 - Office of Neurological and Physical Medicine Devices****PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0	0		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	N/A	N/A	N/A		

**Table 1.11 OHT5 - Office of Neurological and Physical Medicine Devices****PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		

**Table 1.12 OHT5 - Office of Neurological and Physical Medicine Devices****PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		



**Table 1.13 OHT5 - Office of Neurological and Physical Medicine Devices**  
**LDT PMA Original and Panel-Track Supplements MDUFA V Metric\***

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 180 FDA Days	<b>FY 2024</b> 90% Within 180 FDA Days	<b>FY 2025</b> 90% Within 180 FDA Days	<b>FY 2026</b> 90% Within 180 FDA Days	<b>FY 2027</b> 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

\*Includes submission that went to panel

**Table 1.14 OHT5 - Office of Neurological and Physical Medicine Devices**  
**Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric\***

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 320 FDA Days	<b>FY 2024</b> 90% Within 320 FDA Days	<b>FY 2025</b> 90% Within 320 FDA Days	<b>FY 2026</b> 90% Within 320 FDA Days	<b>FY 2027</b> 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

\*Includes submission that went to panel



**Table 1.1 OHT6 - Office of Orthopedic Devices**

**PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	5	3	2		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	4	3	2		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted for Filing Review on First Cycle	1	0	0		
Rate of Submissions Not Accepted for Filing Review on First Cycle	20.00%	0.00%	0.00%		

\*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

**Table 1.2 OHT6 - Office of Orthopedic Devices**

**PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	5	3	2		
Number Accepted	4	3	2		
Completed RTF	5	3	2		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	0.00%	0.00%	0.00%		

**Table 1.3 OHT6 - Office of Orthopedic Devices**

**PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	5	3	2		
SI Goal Met	5	3	2		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%		



**Table 1.4 OHT6 - Office of Orthopedic Devices****PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interactions	5	3	2		
Average Number of FDA Days to Substantive Interaction	85.40	88.00	83.50		
20th Percentile FDA Days to Substantive Interaction	84	87	81		
40th Percentile FDA Days to Substantive Interaction	86	87	83		
60th Percentile FDA Days to Substantive Interaction	87	88	84		
80th Percentile FDA Days to Substantive Interaction	88	89	86		
Maximum FDA Days to Substantive Interaction	88	90	88		

**Table 1.5 OHT6 - Office of Orthopedic Devices****PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 90% Within 180 FDA Days</b>	<b>FY 2024 90% Within 180 FDA Days</b>	<b>FY 2025 90% Within 180 FDA Days</b>	<b>FY 2026 90% Within 180 FDA Days</b>	<b>FY 2027 90% Within 180 FDA Days</b>
Number of PMAs Filed	5	3	2		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	5	2	0		
MDUFA Decision Goal Met	5	2	0		
PMAs Pending MDUFA Decision	0	1	2		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

**Table 1.6 OHT6 - Office of Orthopedic Devices****PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 90% Within 320 FDA Days</b>	<b>FY 2024 90% Within 320 FDA Days</b>	<b>FY 2025 90% Within 320 FDA Days</b>	<b>FY 2026 90% Within 320 FDA Days</b>	<b>FY 2027 90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Goal Met	0	0	0		
PMAs Pending MDUFA Decision	0	0	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	N/A	N/A		



**Table 1.7 OHT6 - Office of Orthopedic Devices**

**PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	5	2	0		
<b>Average FDA Days to MDUFA Decision</b>	173.80	179.00	N/A		
20th Percentile FDA Days to MDUFA Decision	169	178	0		
40th Percentile FDA Days to MDUFA Decision	175	179	0		
60th Percentile FDA Days to MDUFA Decision	178	179	0		
80th Percentile FDA Days to MDUFA Decision	179	180	0		
Maximum FDA Days to MDUFA Decision	180	180	0		
<b>Average Industry Days to MDUFA Decision</b>	194.80	144.50	N/A		
20th Percentile Industry Days to MDUFA Decision	77	144	0		
40th Percentile Industry Days to MDUFA Decision	142	144	0		
60th Percentile Industry Days to MDUFA Decision	243	145	0		
80th Percentile Industry Days to MDUFA Decision	351	145	0		
Maximum Industry Days to MDUFA Decision	356	145	0		
<b>Average Total Days to MDUFA Decision</b>	368.60	323.50	N/A		
20th Percentile Total Days to MDUFA Decision	241	323	0		
40th Percentile Total Days to MDUFA Decision	309	323	0		
60th Percentile Total Days to MDUFA Decision	417	324	0		
80th Percentile Total Days to MDUFA Decision	530	324	0		
Maximum Total Days to MDUFA Decision	536	325	0		



**Table 1.8 OHT6 - Office of Orthopedic Devices**

**PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	0	0	0		
<b>Average FDA Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
<b>Average Industry Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
<b>Average Total Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	0	0	0		



**Table 1.9 OHT6 - Office of Orthopedic Devices****PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	5	3	2		
Number with MDUFA Decision	5	2	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	3	2	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	0.00%	N/A		
Rate of Not Approvable	60.00%	100.00%	N/A		

**Table 1.10 OHT6 - Office of Orthopedic Devices****PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0	0		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	N/A	N/A	N/A		

**Table 1.11 OHT6 - Office of Orthopedic Devices****PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		

**Table 1.12 OHT6 - Office of Orthopedic Devices****PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		



**Table 1.13 OHT6 - Office of Orthopedic Devices**

**LDT PMA Original and Panel-Track Supplements MDUFA V Metric\***

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 180 FDA Days	<b>FY 2024</b> 90% Within 180 FDA Days	<b>FY 2025</b> 90% Within 180 FDA Days	<b>FY 2026</b> 90% Within 180 FDA Days	<b>FY 2027</b> 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

\*Includes submission that went to panel

**Table 1.14 OHT6 - Office of Orthopedic Devices**

**Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric\***

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 320 FDA Days	<b>FY 2024</b> 90% Within 320 FDA Days	<b>FY 2025</b> 90% Within 320 FDA Days	<b>FY 2026</b> 90% Within 320 FDA Days	<b>FY 2027</b> 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

\*Includes submission that went to panel



**Table 1.1 OHT7 - Office of In Vitro Diagnostics**

**PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	16	10		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	21	14	10		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted for Filing Review on First Cycle	0	2	0		
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	12.50%	0.00%		

\*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

**Table 1.2 OHT7 - Office of In Vitro Diagnostics**

**PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	16	10		
Number Accepted	21	14	10		
Completed RTF	21	15	9		
Number Not Filed	1	0	0		
Rate of Submissions Not Filed	4.76%	0.00%	0.00%		

**Table 1.3 OHT7 - Office of In Vitro Diagnostics**

**PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	21	15	9		
SI Goal Met	21	15	5		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	4		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%		



**Table 1.4 OHT7 - Office of In Vitro Diagnostics****PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interactions	21	15	5		
Average Number of FDA Days to Substantive Interaction	88.14	88.60	71.40		
20th Percentile FDA Days to Substantive Interaction	87	88	69		
40th Percentile FDA Days to Substantive Interaction	87	89	86		
60th Percentile FDA Days to Substantive Interaction	89	89	87		
80th Percentile FDA Days to Substantive Interaction	90	90	88		
Maximum FDA Days to Substantive Interaction	90	90	90		

**Table 1.5 OHT7 - Office of In Vitro Diagnostics****PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 90% Within 180 FDA Days</b>	<b>FY 2024 90% Within 180 FDA Days</b>	<b>FY 2025 90% Within 180 FDA Days</b>	<b>FY 2026 90% Within 180 FDA Days</b>	<b>FY 2027 90% Within 180 FDA Days</b>
Number of PMAs Filed	20	15	9		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	20	8	0		
MDUFA Decision Goal Met	20	8	0		
PMAs Pending MDUFA Decision	0	7	9		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

**Table 1.6 OHT7 - Office of In Vitro Diagnostics****PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 90% Within 320 FDA Days</b>	<b>FY 2024 90% Within 320 FDA Days</b>	<b>FY 2025 90% Within 320 FDA Days</b>	<b>FY 2026 90% Within 320 FDA Days</b>	<b>FY 2027 90% Within 320 FDA Days</b>
Number of PMAs Filed	1	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	1	0	0		
MDUFA Decision Goal Met	1	0	0		
PMAs Pending MDUFA Decision	0	0	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	N/A	N/A		



**Table 1.7 OHT7 - Office of In Vitro Diagnostics**

**PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	20	8	0		
<b>Average FDA Days to MDUFA Decision</b>	163.30	169.25	N/A		
20th Percentile FDA Days to MDUFA Decision	136	163	0		
40th Percentile FDA Days to MDUFA Decision	178	179	0		
60th Percentile FDA Days to MDUFA Decision	179	180	0		
80th Percentile FDA Days to MDUFA Decision	180	180	0		
Maximum FDA Days to MDUFA Decision	180	180	0		
<b>Average Industry Days to MDUFA Decision</b>	162.25	33.25	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	68	23	0		
60th Percentile Industry Days to MDUFA Decision	236	41	0		
80th Percentile Industry Days to MDUFA Decision	322	59	0		
Maximum Industry Days to MDUFA Decision	354	84	0		
<b>Average Total Days to MDUFA Decision</b>	325.55	202.50	N/A		
20th Percentile Total Days to MDUFA Decision	179	176	0		
40th Percentile Total Days to MDUFA Decision	247	202	0		
60th Percentile Total Days to MDUFA Decision	364	211	0		
80th Percentile Total Days to MDUFA Decision	502	226	0		
Maximum Total Days to MDUFA Decision	534	244	0		



Table 1.8 OHT7 - Office of In Vitro Diagnostics

## PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	1	0	0		
<b>Average FDA Days to MDUFA Decision</b>	318.00	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	318	0	0		
40th Percentile FDA Days to MDUFA Decision	318	0	0		
60th Percentile FDA Days to MDUFA Decision	318	0	0		
80th Percentile FDA Days to MDUFA Decision	318	0	0		
Maximum FDA Days to MDUFA Decision	318	0	0		
<b>Average Industry Days to MDUFA Decision</b>	186.00	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	186	0	0		
40th Percentile Industry Days to MDUFA Decision	186	0	0		
60th Percentile Industry Days to MDUFA Decision	186	0	0		
80th Percentile Industry Days to MDUFA Decision	186	0	0		
Maximum Industry Days to MDUFA Decision	186	0	0		
<b>Average Total Days to MDUFA Decision</b>	504.00	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	504	0	0		
40th Percentile Total Days to MDUFA Decision	504	0	0		
60th Percentile Total Days to MDUFA Decision	504	0	0		
80th Percentile Total Days to MDUFA Decision	504	0	0		
Maximum Total Days to MDUFA Decision	504	0	0		



**Table 1.9 OHT7 - Office of In Vitro Diagnostics****PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	20	15	9		
Number with MDUFA Decision	20	8	0		
Number of Withdrawal	1	1	0		
Number of Not Approvable	3	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	5.00%	12.50%	#DIV/0!		
Rate of Not Approvable	15.00%	0.00%	#DIV/0!		

**Table 1.10 OHT7 - Office of In Vitro Diagnostics****PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	1	0	0		
Number With MDUFA Decision	1	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	N/A	N/A		
Rate of Not Approvable	0.00%	N/A	N/A		

**Table 1.11 OHT7 - Office of In Vitro Diagnostics****PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		

**Table 1.12 OHT7 - Office of In Vitro Diagnostics****PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		



**Table 1.13 OHT7 - Office of In Vitro Diagnostics**

**LDT PMA Original and Panel-Track Supplements MDUFA V Metric\***

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 180 FDA Days	<b>FY 2024</b> 90% Within 180 FDA Days	<b>FY 2025</b> 90% Within 180 FDA Days	<b>FY 2026</b> 90% Within 180 FDA Days	<b>FY 2027</b> 90% Within 180 FDA Days
Number of PMAs Filed	6	5	3		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	6	2	0		
MDUFA Decision Goal Met	6	2	0		
PMAs Pending MDUFA Decision	0	3	3		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

\*Includes submission that went to panel

**Table 1.14 OHT7 - Office of In Vitro Diagnostics**

**Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric\***

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 320 FDA Days	<b>FY 2024</b> 90% Within 320 FDA Days	<b>FY 2025</b> 90% Within 320 FDA Days	<b>FY 2026</b> 90% Within 320 FDA Days	<b>FY 2027</b> 90% Within 320 FDA Days
Number of PMAs Filed	15	10	6		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	15	6	0		
MDUFA Decision Goal Met	15	6	0		
PMAs Pending MDUFA Decision	0	4	6		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

\*Includes submission that went to panel



**Table 1.1 OHT8 - Office of Radiological Health****PMA Original and Panel-Track Supplements - Acceptance Review Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	0	3	0		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	0	3	0		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted for Filing Review on First Cycle	0	0	0		
Rate of Submissions Not Accepted for Filing Review on First Cycle	N/A	0.00%	N/A		

\*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

**Table 1.2 OHT8 - Office of Radiological Health****PMA Original and Panel-Track Supplements - Filing Review Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	0	3	0		
Number Accepted	0	3	0		
Completed RTF	0	3	0		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	N/A	0.00%	N/A		

**Table 1.3 OHT8 - Office of Radiological Health****PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

<b>Substantive Interaction (SI) Goal</b>	<b>FY 2023 95% SI Within 90 FDA Days</b>	<b>FY 2024 95% SI Within 90 FDA Days</b>	<b>FY 2025 95% SI Within 90 FDA Days</b>	<b>FY 2026 95% SI Within 90 FDA Days</b>	<b>FY 2027 95% SI Within 90 FDA Days</b>
Eligible for SI	0	3	0		
SI Goal Met	0	3	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	N/A	100.00%	N/A		



**Table 1.4 OHT8 - Office of Radiological Health****PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interactions	0	3	0		
Average Number of FDA Days to Substantive Interaction	N/A	89.33	N/A		
20th Percentile FDA Days to Substantive Interaction	0	89	0		
40th Percentile FDA Days to Substantive Interaction	0	90	0		
60th Percentile FDA Days to Substantive Interaction	0	90	0		
80th Percentile FDA Days to Substantive Interaction	0	90	0		
Maximum FDA Days to Substantive Interaction	0	90	0		

**Table 1.5 OHT8 - Office of Radiological Health****PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 90% Within 180 FDA Days</b>	<b>FY 2024 90% Within 180 FDA Days</b>	<b>FY 2025 90% Within 180 FDA Days</b>	<b>FY 2026 90% Within 180 FDA Days</b>	<b>FY 2027 90% Within 180 FDA Days</b>
Number of PMAs Filed	0	3	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Goal Met	0	0	0		
PMAs Pending MDUFA Decision	0	3	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	N/A	N/A		

**Table 1.6 OHT8 - Office of Radiological Health****PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 90% Within 320 FDA Days</b>	<b>FY 2024 90% Within 320 FDA Days</b>	<b>FY 2025 90% Within 320 FDA Days</b>	<b>FY 2026 90% Within 320 FDA Days</b>	<b>FY 2027 90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Goal Met	0	0	0		
PMAs Pending MDUFA Decision	0	0	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	N/A	N/A		



Table 1.7 OHT8 - Office of Radiological Health

**PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	0	0	0		
<b>Average FDA Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
<b>Average Industry Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
<b>Average Total Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	0	0	0		



Table 1.8 OHT8 - Office of Radiological Health

**PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	0	0	0		
<b>Average FDA Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
<b>Average Industry Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
<b>Average Total Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	0	0	0		



**Table 1.9 OHT8 - Office of Radiological Health****PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	3	0		
Number with MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	N/A	N/A	N/A		

**Table 1.10 OHT8 - Office of Radiological Health****PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0	0		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	N/A	N/A	N/A		

**Table 1.11 OHT8 - Office of Radiological Health****PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		

**Table 1.12 OHT8 - Office of Radiological Health****PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		



**Table 1.13 OHT8 - Office of Radiological Health**

**LDT PMA Original and Panel-Track Supplements MDUFA V Metric\***

<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 180 FDA Days	<b>FY 2024</b> 90% Within 180 FDA Days	<b>FY 2025</b> 90% Within 180 FDA Days	<b>FY 2026</b> 90% Within 180 FDA Days	<b>FY 2027</b> 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

\*Includes submission that went to panel

**Table 1.14 OHT8 - Office of Radiological Health**

**Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric\***

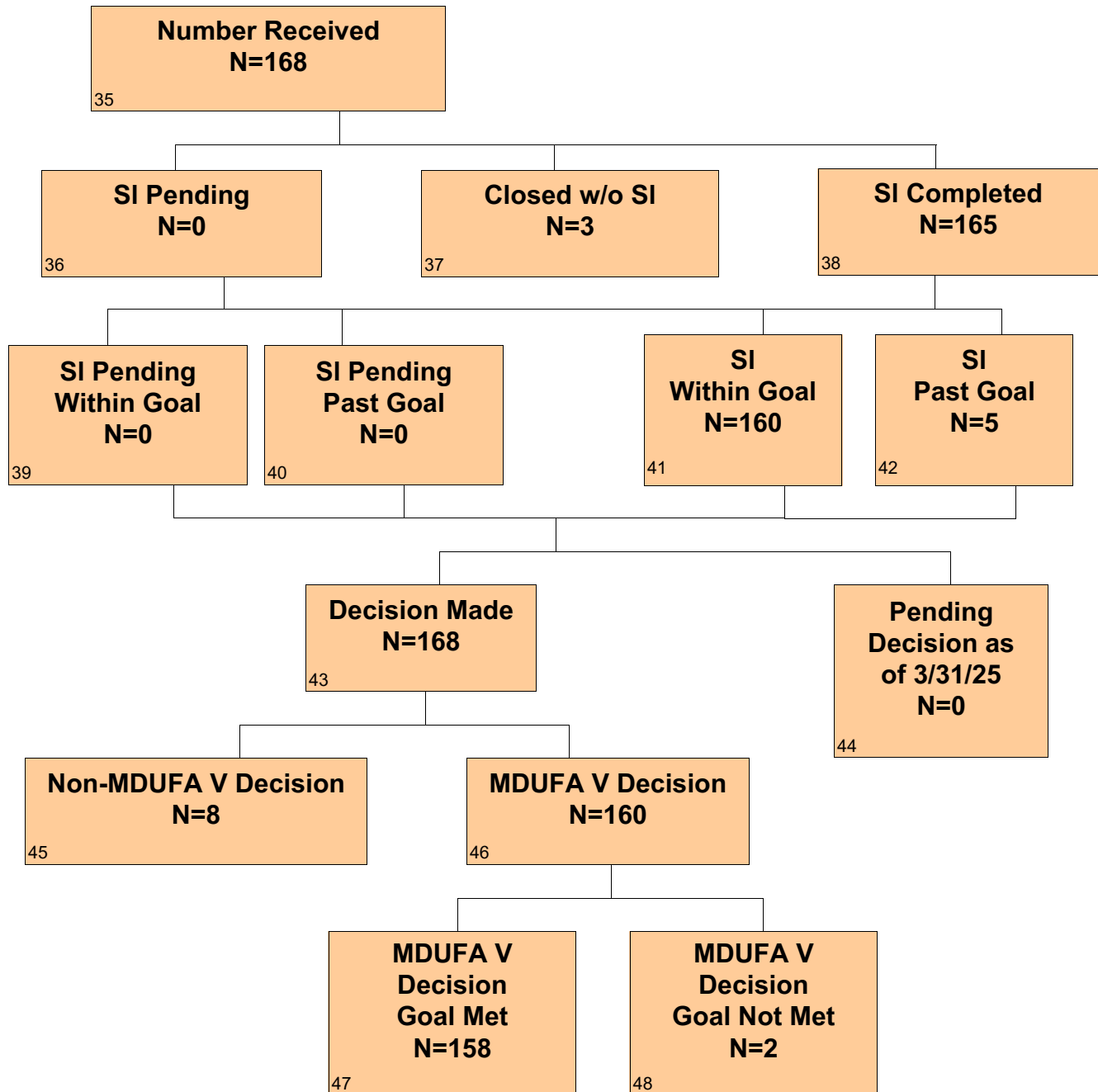
<b>Performance Metric</b>	<b>FY 2023</b> 90% Within 320 FDA Days	<b>FY 2024</b> 90% Within 320 FDA Days	<b>FY 2025</b> 90% Within 320 FDA Days	<b>FY 2026</b> 90% Within 320 FDA Days	<b>FY 2027</b> 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

\*Includes submission that went to panel



# CDRH PMA 180 Day Supplements - FY 2023 as of 3/31/25

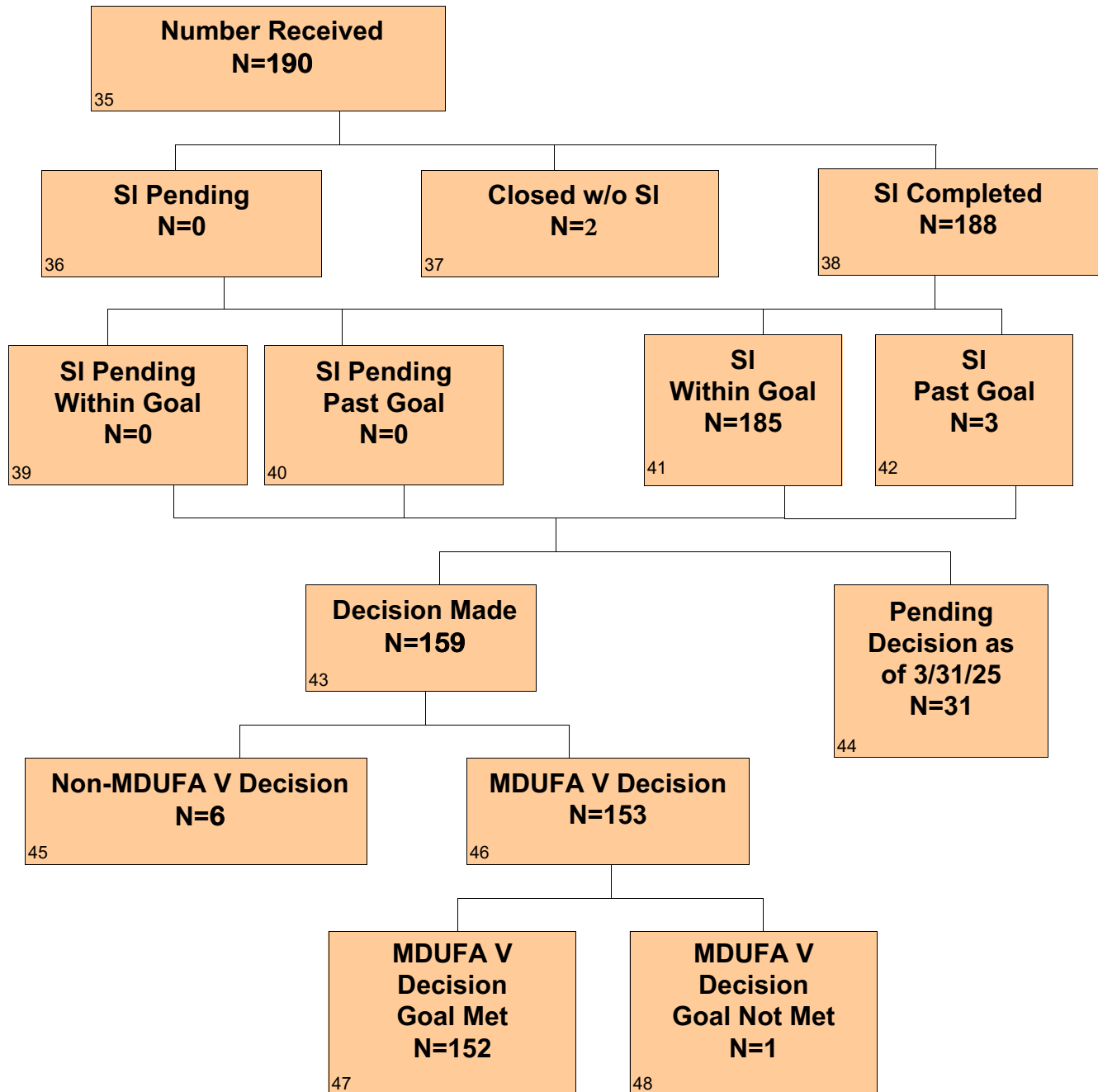
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# CDRH PMA 180 Day Supplements - FY 2024 as of 3/31/25

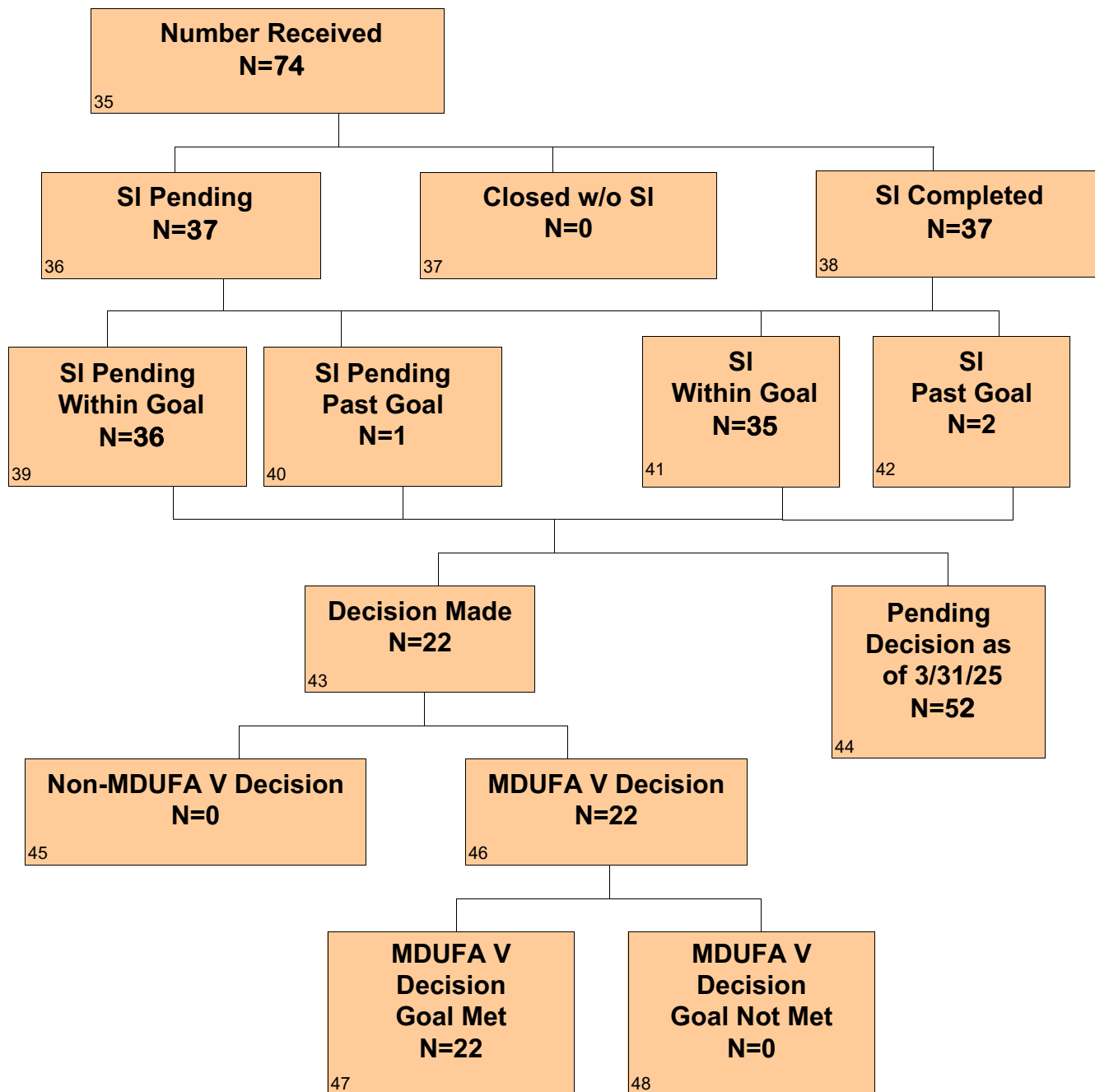
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# CDRH PMA 180 Day Supplements - FY 2025 as of 3/31/25

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## Section 2 PMA 180-Day Supplements - Center Level Metric

**Table 2.1 CDRH - PMA 180-Day Supplements Substantive Interaction Goal**

<b>Substantive Interaction (SI) Goal</b>	<b>FY 2023</b> 95% SI Within 90 FDA Days	<b>FY 2024</b> 95% SI Within 90 FDA Days	<b>FY 2025</b> 95% SI Within 90 FDA Days	<b>FY 2026</b> 95% SI Within 90 FDA Days	<b>FY 2027</b> 95% SI Within 90 FDA Days
Eligible for SI	168	190	74		
SI Goal Met	160	185	35		
SI Goal Not Met	5	3	2		
SI Pending Within Goal	0	0	36		
SI Pending Past Goal	0	0	1		
Closed Without SI	3	2	0		
Current SI Performance Percent Goal Met	96.97%	98.40%	92.11%		

**Table 2.2 CDRH - PMA 180-Day Supplements MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b> 95% Within 180 FDA Days	<b>FY 2024</b> 95% Within 180 FDA Days	<b>FY 2025</b> 95% Within 180 FDA Days	<b>FY 2026</b> 95% Within 180 FDA Days	<b>FY 2027</b> 95% Within 180 FDA Days
Supplements Received	168	190	74		
Non-MDUFA Decision	8	6	0		
MDUFA Decision	160	153	22		
MDUFA Decision Goal Met	158	152	22		
Supplements Pending MDUFA Decision	0	31	52		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	98.75%	99.35%	100.00%		

**Table 2.3 CDRH - PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	168	190	74		
Number with MDUFA Decision	160	153	22		
Number of Not Approvable	8	12	0		
Rate of Not Approvable	5.00%	7.84%	0.00%		

**Table 2.4 CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Submissions that Missed the Goal	2	4	0		
Mean FDA Days for Submissions that Missed the Goal	197.00	189.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	77.00	32.25	N/A		



## Section 2 PMA 180-Day Supplements - Office Level Metric

**Table 2.1 OHT1 - - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device**  
**PMA 180-Day Supplements Substantive Interaction Goal**

<b>Substantive Interaction (SI) Goal</b>	<b>FY 2023</b> 95% SI Within 90 FDA Days	<b>FY 2024</b> 95% SI Within 90 FDA Days	<b>FY 2025</b> 95% SI Within 90 FDA Days	<b>FY 2026</b> 95% SI Within 90 FDA Days	<b>FY 2027</b> 95% SI Within 90 FDA Days
Eligible for SI	16	15	10		
SI Goal Met	16	15	3		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	7		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%		

**Table 2.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device**  
**PMA 180-Day Supplements MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b> 95% Within 180 FDA Days	<b>FY 2024</b> 95% Within 180 FDA Days	<b>FY 2025</b> 95% Within 180 FDA Days	<b>FY 2026</b> 95% Within 180 FDA Days	<b>FY 2027</b> 95% Within 180 FDA Days
Supplements Received	16	15	10		
Non-MDUFA Decision	1	0	0		
MDUFA Decision	15	7	3		
MDUFA Decision Goal Met	15	7	3		
Supplements Pending MDUFA Decision	0	8	7		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

**Table 2.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device**  
**PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	16	15	10		
Number with MDUFA Decision	15	7	3		
Number of Not Approvable	1	1	0		
Rate of Not Approvable	6.67%	14.29%	0.00%		

**Table 2.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device**  
**PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	0.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	0.00	N/A		



**Table 2.1 OHT2 - Office of Cardiovascular Devices**  
**PMA 180-Day Supplements Substantive Interaction Goal**

<b>Substantive Interaction (SI) Goal</b>	<b>FY 2023</b> 95% SI Within 90 FDA Days	<b>FY 2024</b> 95% SI Within 90 FDA Days	<b>FY 2025</b> 95% SI Within 90 FDA Days	<b>FY 2026</b> 95% SI Within 90 FDA Days	<b>FY 2027</b> 95% SI Within 90 FDA Days
Eligible for SI	56	81	22		
SI Goal Met	55	80	6		
SI Goal Not Met	0	0	2		
SI Pending Within Goal	0	0	14		
SI Pending Past Goal	0	0	0		
Closed Without SI	1	1	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	75.00%		

**Table 2.2 OHT2 - Office of Cardiovascular Devices**  
**PMA 180-Day Supplements MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b> 95% Within 180 FDA Days	<b>FY 2024</b> 95% Within 180 FDA Days	<b>FY 2025</b> 95% Within 180 FDA Days	<b>FY 2026</b> 95% Within 180 FDA Days	<b>FY 2027</b> 95% Within 180 FDA Days
Supplements Received	56	81	22		
Non-MDUFA Decision	3	4	0		
MDUFA Decision	53	67	5		
MDUFA Decision Goal Met	53	67	5		
Supplements Pending MDUFA Decision	0	10	17		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

**Table 2.3 OHT2 - Office of Cardiovascular Devices**  
**PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	56	81	22		
Number with MDUFA Decision	53	67	5		
Number of Not Approvable	1	10	0		
Rate of Not Approvable	1.89%	14.93%	0.00%		

**Table 2.4 OHT2 - Office of Cardiovascular Devices**  
**PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Submissions that Missed the Goal	0	3	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	186.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	0.00	N/A		



**Table 2.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**PMA 180-Day Supplements Substantive Interaction Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	21	17	11		
SI Goal Met	20	17	8		
SI Goal Not Met	1	0	0		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	1		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	95.24%	100.00%	88.89%		

**Table 2.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**PMA 180-Day Supplements MDUFA V Decision**

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	21	17	11		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	21	17	7		
MDUFA Decision Goal Met	21	17	7		
Supplements Pending MDUFA Decision	0	0	4		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

**Table 2.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	17	11		
Number with MDUFA Decision	21	17	7		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.00%	0.00%	0.00%		

**Table 2.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		



**Table 2.1 OHT4 - Office of Surgical and Infection Control Devices**  
**PMA 180-Day Supplements Substantive Interaction Goal**

<b>Substantive Interaction (SI) Goal</b>	<b>FY 2023</b> 95% SI Within 90 FDA Days	<b>FY 2024</b> 95% SI Within 90 FDA Days	<b>FY 2025</b> 95% SI Within 90 FDA Days	<b>FY 2026</b> 95% SI Within 90 FDA Days	<b>FY 2027</b> 95% SI Within 90 FDA Days
Eligible for SI	8	12	5		
SI Goal Met	8	12	1		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	4		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%		

**Table 2.2 OHT4 - Office of Surgical and Infection Control Devices**  
**PMA 180-Day Supplements MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b> 95% Within 180 FDA Days	<b>FY 2024</b> 95% Within 180 FDA Days	<b>FY 2025</b> 95% Within 180 FDA Days	<b>FY 2026</b> 95% Within 180 FDA Days	<b>FY 2027</b> 95% Within 180 FDA Days
Supplements Received	8	12	5		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	8	10	1		
MDUFA Decision Goal Met	8	10	1		
Supplements Pending MDUFA Decision	0	2	4		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

**Table 2.3 OHT4 - Office of Surgical and Infection Control Devices**  
**PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	8	12	5		
Number with MDUFA Decision	8	10	1		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.00%	0.00%	0.00%		

**Table 2.4 OHT4 - Office of Surgical and Infection Control Devices**  
**PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		



**Table 2.1 OHT5 - Office of Neurological and Physical Medicine Devices**  
**PMA 180-Day Supplements Substantive Interaction Goal**

<b>Substantive Interaction (SI) Goal</b>	<b>FY 2023</b> 95% SI Within 90 FDA Days	<b>FY 2024</b> 95% SI Within 90 FDA Days	<b>FY 2025</b> 95% SI Within 90 FDA Days	<b>FY 2026</b> 95% SI Within 90 FDA Days	<b>FY 2027</b> 95% SI Within 90 FDA Days
Eligible for SI	23	20	8		
SI Goal Met	20	17	4		
SI Goal Not Met	3	3	0		
SI Pending Within Goal	0	0	4		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	86.96%	85.00%	100.00%		

**Table 2.2 OHT5 - Office of Neurological and Physical Medicine Devices**  
**PMA 180-Day Supplements MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b> 95% Within 180 FDA Days	<b>FY 2024</b> 95% Within 180 FDA Days	<b>FY 2025</b> 95% Within 180 FDA Days	<b>FY 2026</b> 95% Within 180 FDA Days	<b>FY 2027</b> 95% Within 180 FDA Days
Supplements Received	23	20	8		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	23	17	3		
MDUFA Decision Goal Met	21	16	3		
Supplements Pending MDUFA Decision	0	3	5		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	91.30%	94.12%	100.00%		

**Table 2.3 OHT5 - Office of Neurological and Physical Medicine Devices**  
**PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	23	20	8		
Number with MDUFA Decision	23	17	3		
Number of Not Approvable	3	0	0		
Rate of Not Approvable	13.04%	0.00%	0.00%		

**Table 2.4 OHT5 - Office of Neurological and Physical Medicine Devices**  
**PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Submissions that Missed the Goal	2	1	0		
Mean FDA Days for Submissions that Missed the Goal	197.00	198.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	77.00	129.00	N/A		



**Table 2.1 OHT6 - Office of Orthopedic Devices**  
**PMA 180-Day Supplements Substantive Interaction Goal**

<b>Substantive Interaction (SI) Goal</b>	<b>FY 2023</b> 95% SI Within 90 FDA Days	<b>FY 2024</b> 95% SI Within 90 FDA Days	<b>FY 2025</b> 95% SI Within 90 FDA Days	<b>FY 2026</b> 95% SI Within 90 FDA Days	<b>FY 2027</b> 95% SI Within 90 FDA Days
Eligible for SI	7	5	6		
SI Goal Met	7	5	3		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	3		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%		

**Table 2.2 OHT6 - Office of Orthopedic Devices**  
**PMA 180-Day Supplements MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b> 95% Within 180 FDA Days	<b>FY 2024</b> 95% Within 180 FDA Days	<b>FY 2025</b> 95% Within 180 FDA Days	<b>FY 2026</b> 95% Within 180 FDA Days	<b>FY 2027</b> 95% Within 180 FDA Days
Supplements Received	7	5	6		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	7	5	2		
MDUFA Decision Goal Met	7	5	2		
Supplements Pending MDUFA Decision	0	0	4		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

**Table 2.3 OHT6 - Office of Orthopedic Devices**  
**PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	7	5	6		
Number with MDUFA Decision	7	5	2		
Number of Not Approvable	1	0	0		
Rate of Not Approvable	14.29%	0.00%	0.00%		

**Table 2.4 OHT6 - Office of Orthopedic Devices**  
**PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		



**Table 2.1 OHT7 - Office of In Vitro Diagnostics**  
**PMA 180-Day Supplements Substantive Interaction Goal**

<b>Substantive Interaction (SI) Goal</b>	<b>FY 2023</b> 95% SI Within 90 FDA Days	<b>FY 2024</b> 95% SI Within 90 FDA Days	<b>FY 2025</b> 95% SI Within 90 FDA Days	<b>FY 2026</b> 95% SI Within 90 FDA Days	<b>FY 2027</b> 95% SI Within 90 FDA Days
Eligible for SI	36	38	12		
SI Goal Met	33	37	10		
SI Goal Not Met	1	0	0		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	0		
Closed Without SI	2	1	0		
Current SI Performance Percent Goal Met	97.06%	100.00%	100.00%		

**Table 2.2 OHT7 - Office of In Vitro Diagnostics**  
**PMA 180-Day Supplements MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b> 95% Within 180 FDA Days	<b>FY 2024</b> 95% Within 180 FDA Days	<b>FY 2025</b> 95% Within 180 FDA Days	<b>FY 2026</b> 95% Within 180 FDA Days	<b>FY 2027</b> 95% Within 180 FDA Days
Supplements Received	36	38	12		
Non-MDUFA Decision	4	2	0		
MDUFA Decision	32	28	1		
MDUFA Decision Goal Met	32	28	1		
Supplements Pending MDUFA Decision	0	8	11		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

**Table 2.3 OHT7 - Office of In Vitro Diagnostics**  
**PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	36	38	12		
Number with MDUFA Decision	32	28	1		
Number of Not Approvable	2	1	0		
Rate of Not Approvable	6.25%	3.57%	0.00%		

**Table 2.4 OHT7 - Office of In Vitro Diagnostics**  
**PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		



**Table 2.1 OHT8 - Office of Radiological Health**  
**PMA 180-Day Supplements Substantive Interaction Goal**

<b>Substantive Interaction (SI) Goal</b>	<b>FY 2023</b> 95% SI Within 90 FDA Days	<b>FY 2024</b> 95% SI Within 90 FDA Days	<b>FY 2025</b> 95% SI Within 90 FDA Days	<b>FY 2026</b> 95% SI Within 90 FDA Days	<b>FY 2027</b> 95% SI Within 90 FDA Days
Eligible for SI	1	2	0		
SI Goal Met	1	2	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	N/A		

**Table 2.2 OHT8 - Office of Radiological Health**  
**PMA 180-Day Supplements MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b> 95% Within 180 FDA Days	<b>FY 2024</b> 95% Within 180 FDA Days	<b>FY 2025</b> 95% Within 180 FDA Days	<b>FY 2026</b> 95% SI Within 90 FDA Days	<b>FY 2027</b> 95% SI Within 90 FDA Days
Supplements Received	1	2	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	1	2	0		
MDUFA Decision Goal Met	1	2	0		
Supplements Pending MDUFA Decision	0	0	0		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

**Table 2.3 OHT8 - Office of Radiological Health**  
**PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	1	2	0		
Number with MDUFA Decision	1	2	0		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.00%	0.00%	N/A		

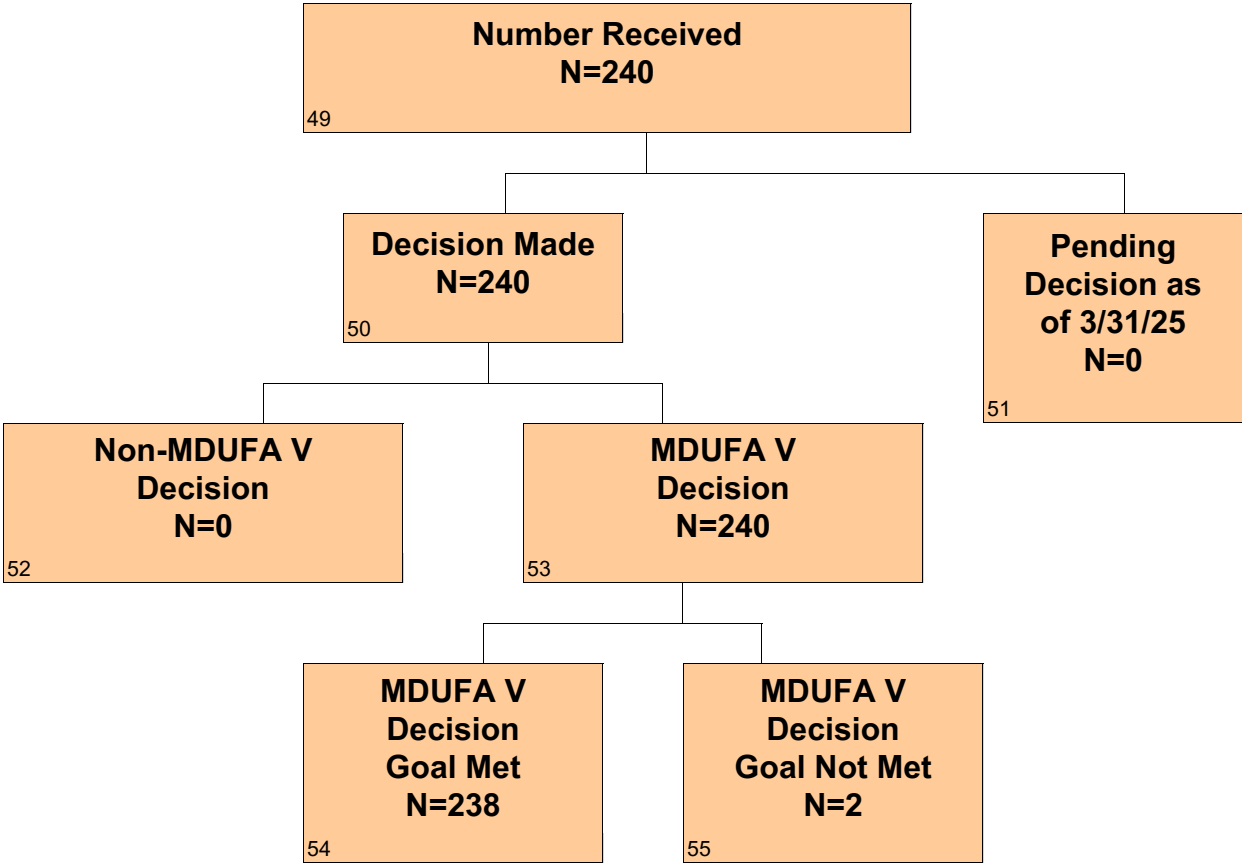
**Table 2.4 OHT8 - Office of Radiological Health**  
**PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		



# CDRH PMA Real Time Supplements - FY 2023 as of 3/31/25

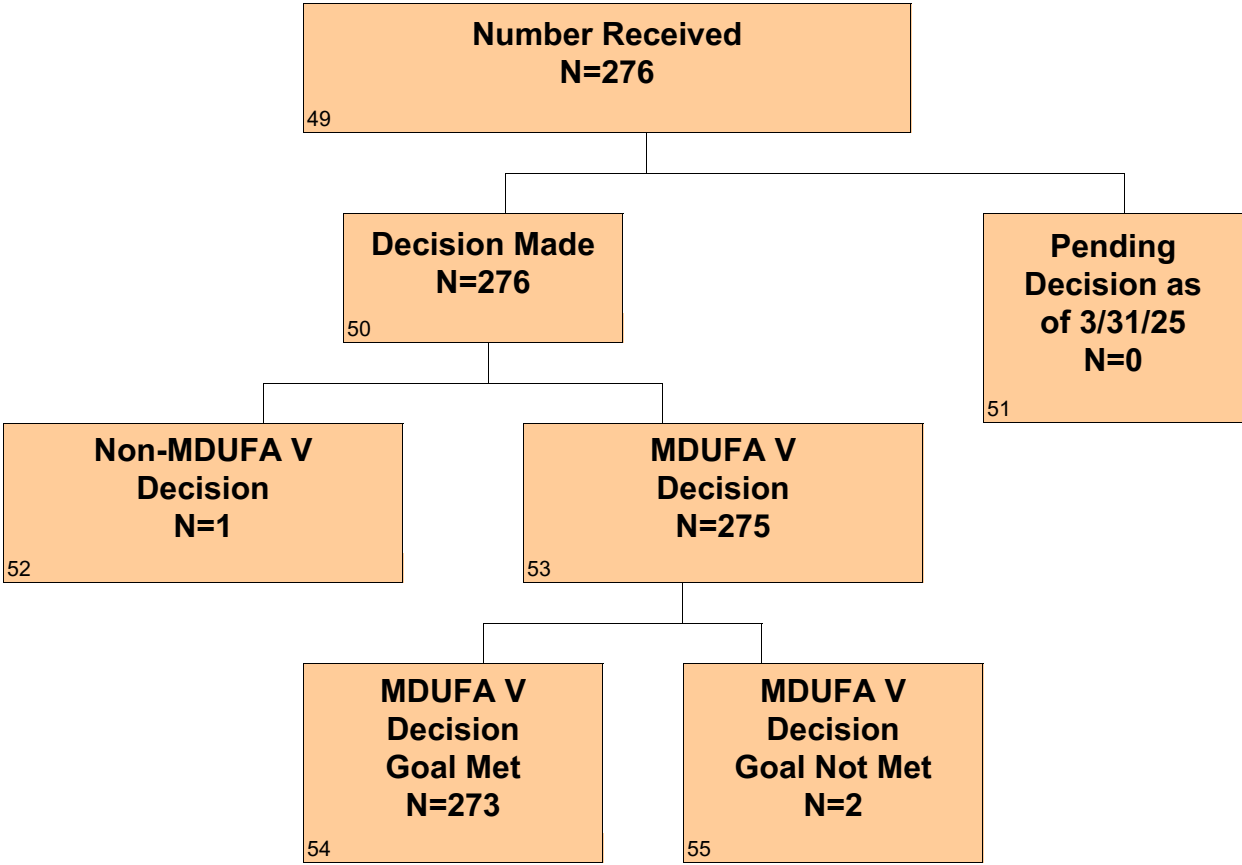
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# CDRH PMA Real Time Supplements - FY 2024 as of 3/31/25

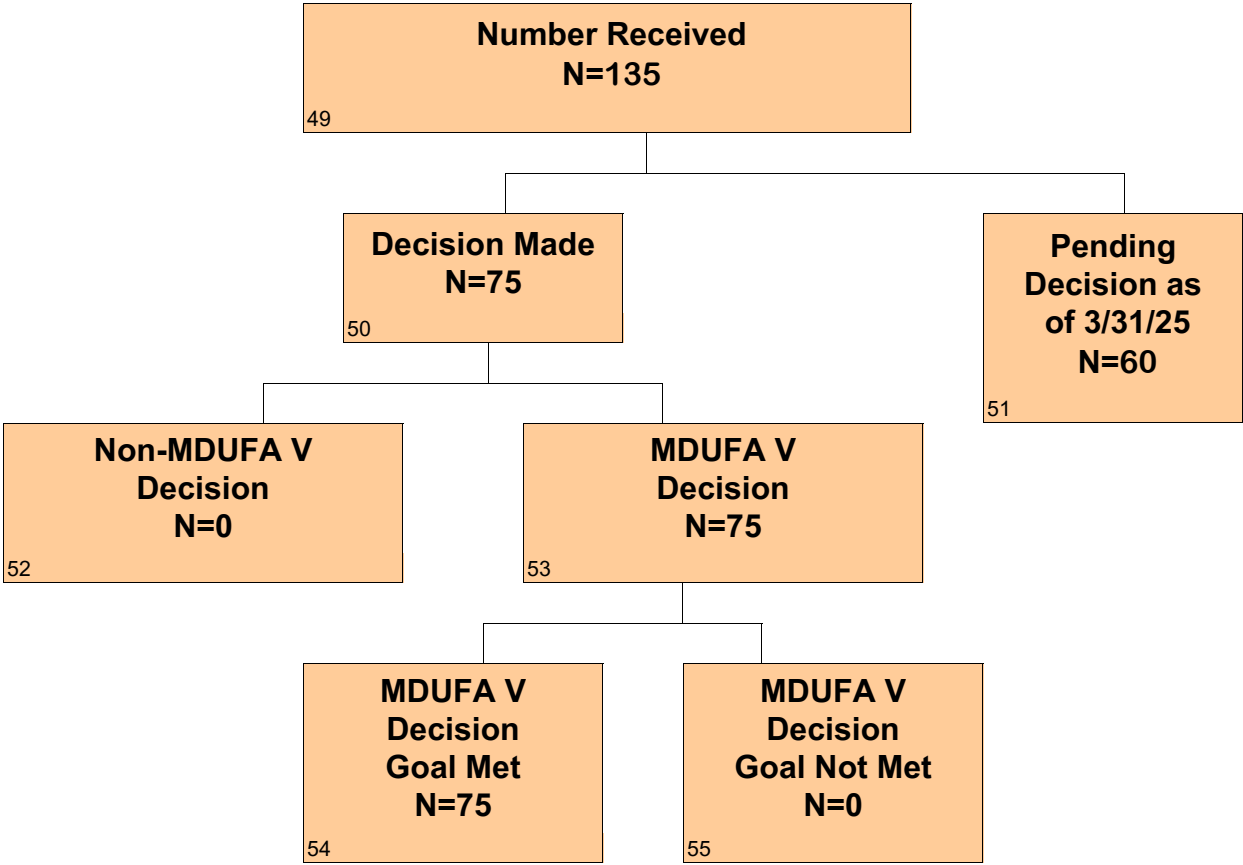
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# CDRH PMA Real Time Supplements - FY 2025 as of 3/31/25

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### Section 3 PMA Real-Time Supplements - Center Level Metric

**Table 3.1 CDRH - PMA Real-Time Supplements MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 95% Within 90 FDA Days</b>	<b>FY 2024 95% Within 90 FDA Days</b>	<b>FY 2025 95% Within 90 FDA Days</b>	<b>FY 2026 95% Within 90 FDA Days</b>	<b>FY 2027 95% Within 90 FDA Days</b>
Supplements Received	240	276	135		
Non-MDUFA Decision	0	1	0		
MDUFA Decision	240	275	75		
MDUFA Decision Goal Met	238	273	75		
Supplements Pending MDUFA Decision	0	0	60		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	99.17%	99.27%	100.00%		

**Table 3.2 CDRH - PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	240	276	135		
Number With MDUFA Decision	240	275	75		
Number of Not Approvable	11	10	4		
Rate of Not Approvable	4.58%	3.64%	5.33%		

**Table 3.3 CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Submissions that Missed the Goal	2	2	0		
Mean FDA Days for Submissions that Missed the Goal	109.50	119.50	N/A		
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	N/A		



### Section 3 PMA Real-Time Supplements - Office Level Metric

**Table 3.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
PMA Real-Time Supplements MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	24	19	16		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	24	19	9		
MDUFA Decision Goal Met	24	19	9		
Supplements Pending MDUFA Decision	0	0	7		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

**Table 3.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	24	19	16		
Number With MDUFA Decision	24	19	9		
Number of Not Approvable	3	2	1		
Rate of Not Approvable	12.50%	10.53%	11.11%		

**Table 3.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	0.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	0.00	N/A		



**Table 3.1 OHT2 - Office of Cardiovascular Devices**

**PMA Real-Time Supplements MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 95% Within 90 FDA Days</b>	<b>FY 2024 95% Within 90 FDA Days</b>	<b>FY 2025 95% Within 90 FDA Days</b>	<b>FY 2026 95% Within 90 FDA Days</b>	<b>FY 2027 95% Within 90 FDA Days</b>
Supplements Received	136	142	59		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	136	142	32		
MDUFA Decision Goal Met	136	142	32		
Supplements Pending MDUFA Decision	0	0	27		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

**Table 3.2 OHT2 - Office of Cardiovascular Devices**

**PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	136	142	59		
Number With MDUFA Decision	136	142	32		
Number of Not Approvable	4	1	3		
Rate of Not Approvable	2.94%	0.70%	9.38%		

**Table 3.3 OHT2 - Office of Cardiovascular Devices**

**PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	0.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	0.00	N/A		



**Table 3.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**PMA Real-Time Supplements MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 95% Within 90 FDA Days</b>	<b>FY 2024 95% Within 90 FDA Days</b>	<b>FY 2025 95% Within 90 FDA Days</b>	<b>FY 2026 95% Within 90 FDA Days</b>	<b>FY 2027 95% Within 90 FDA Days</b>
Supplements Received	19	23	6		
Non-MDUFA Decision	0	1	0		
MDUFA Decision	19	22	0		
MDUFA Decision Goal Met	18	21	0		
Supplements Pending MDUFA Decision	0	0	0		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	94.74%	95.45%	N/A		

**Table 3.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	19	23	6		
Number With MDUFA Decision	19	22	4		
Number of Not Approvable	2	4	0		
Rate of Not Approvable	10.53%	18.18%	0.00%		

**Table 3.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Submissions that Missed the Goal	1	1	0		
Mean FDA Days for Submissions that Missed the Goal	92.00	91.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	N/A		



**Table 3.1 OHT4 - Office of Surgical and Infection Control Devices**  
**PMA Real-Time Supplements MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	7	10	6		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	7	10	4		
MDUFA Decision Goal Met	7	10	4		
Supplements Pending MDUFA Decision	0	0	2		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

**Table 3.2 OHT4 - Office of Surgical and Infection Control Devices**  
**PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	7	10	6		
Number With MDUFA Decision	7	10	4		
Number of Not Approvable	2	1	0		
Rate of Not Approvable	28.57%	10.00%	0.00%		

**Table 3.3 OHT4 - Office of Surgical and Infection Control Devices**  
**PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	0.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	0.00	N/A		



**Table 3.1 OHT5 - Office of Neurological and Physical Medicine Devices**  
**PMA Real-Time Supplements MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 95% Within 90 FDA Days</b>	<b>FY 2024 95% Within 90 FDA Days</b>	<b>FY 2025 95% Within 90 FDA Days</b>	<b>FY 2026 95% Within 90 FDA Days</b>	<b>FY 2027 95% Within 90 FDA Days</b>
Supplements Received	16	37	31		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	16	37	21		
MDUFA Decision Goal Met	15	36	21		
Supplements Pending MDUFA Decision	0	0	10		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	93.75%	97.30%	100.00%		

**Table 3.2 OHT5 - Office of Neurological and Physical Medicine Devices**  
**PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	16	37	31		
Number With MDUFA Decision	16	37	21		
Number of Not Approvable	0	1	0		
Rate of Not Approvable	0.00%	2.70%	0.00%		

**Table 3.3 OHT5 - Office of Neurological and Physical Medicine Devices**  
**PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Submissions that Missed the Goal	1	1	0		
Mean FDA Days for Submissions that Missed the Goal	127.00	148.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	N/A		



**Table 3.1 OHT6 - Office of Orthopedic Devices**

**PMA Real-Time Supplements MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 95% Within 90 FDA Days</b>	<b>FY 2024 95% Within 90 FDA Days</b>	<b>FY 2025 95% Within 90 FDA Days</b>	<b>FY 2026 95% Within 90 FDA Days</b>	<b>FY 2027 95% Within 90 FDA Days</b>
Supplements Received	4	11	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	4	11	0		
MDUFA Decision Goal Met	4	11	0		
Supplements Pending MDUFA Decision	0	0	0		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

**Table 3.2 OHT6 - Office of Orthopedic Devices**

**PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	4	11	0		
Number With MDUFA Decision	4	11	0		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.00%	0.00%	N/A		

**Table 3.3 OHT6 - Office of Orthopedic Devices**

**PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	0.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	0.00	N/A		



**Table 3.1 OHT7 - Office of In Vitro Diagnostics**

**PMA Real-Time Supplements MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 95% Within 90 FDA Days</b>	<b>FY 2024 95% Within 90 FDA Days</b>	<b>FY 2025 95% Within 90 FDA Days</b>	<b>FY 2026 95% Within 90 FDA Days</b>	<b>FY 2027 95% Within 90 FDA Days</b>
Supplements Received	32	33	17		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	32	33	5		
MDUFA Decision Goal Met	32	33	5		
Supplements Pending MDUFA Decision	0	0	12		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

**Table 3.2 OHT7 - Office of In Vitro Diagnostics**

**PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	32	33	17		
Number With MDUFA Decision	32	33	5		
Number of Not Approvable	0	1	0		
Rate of Not Approvable	0.00%	3.03%	0.00%		

**Table 3.3 OHT7 - Office of In Vitro Diagnostics**

**PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	0.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	0.00	N/A		



**Table 3.1 OHT8 - Office of Radiological Health**

**PMA Real-Time Supplements MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 95% Within 90 FDA Days</b>	<b>FY 2024 95% Within 90 FDA Days</b>	<b>FY 2025 95% Within 90 FDA Days</b>	<b>FY 2026 95% Within 90 FDA Days</b>	<b>FY 2027 95% Within 90 FDA Days</b>
Supplements Received	2	1	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	2	1	0		
MDUFA Decision Goal Met	2	1	0		
Supplements Pending MDUFA Decision	0	0	0		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

**Table 3.2 OHT8 - Office of Radiological Health**

**PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	2	1	0		
Number With MDUFA Decision	2	1	0		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.00%	0.00%	N/A		

**Table 3.3 OHT8 - Office of Radiological Health**

**PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	0.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	0.00	N/A		



## **Section 4 Pre-Market Report Submissions**

There were no pre-market reports received by FDA between January 1, 2025 and March 31, 2025.



## **Section 5 PMA Annual Metrics and Goals**

PMA Annual Metrics and Goals will be reported in the Annual Report.

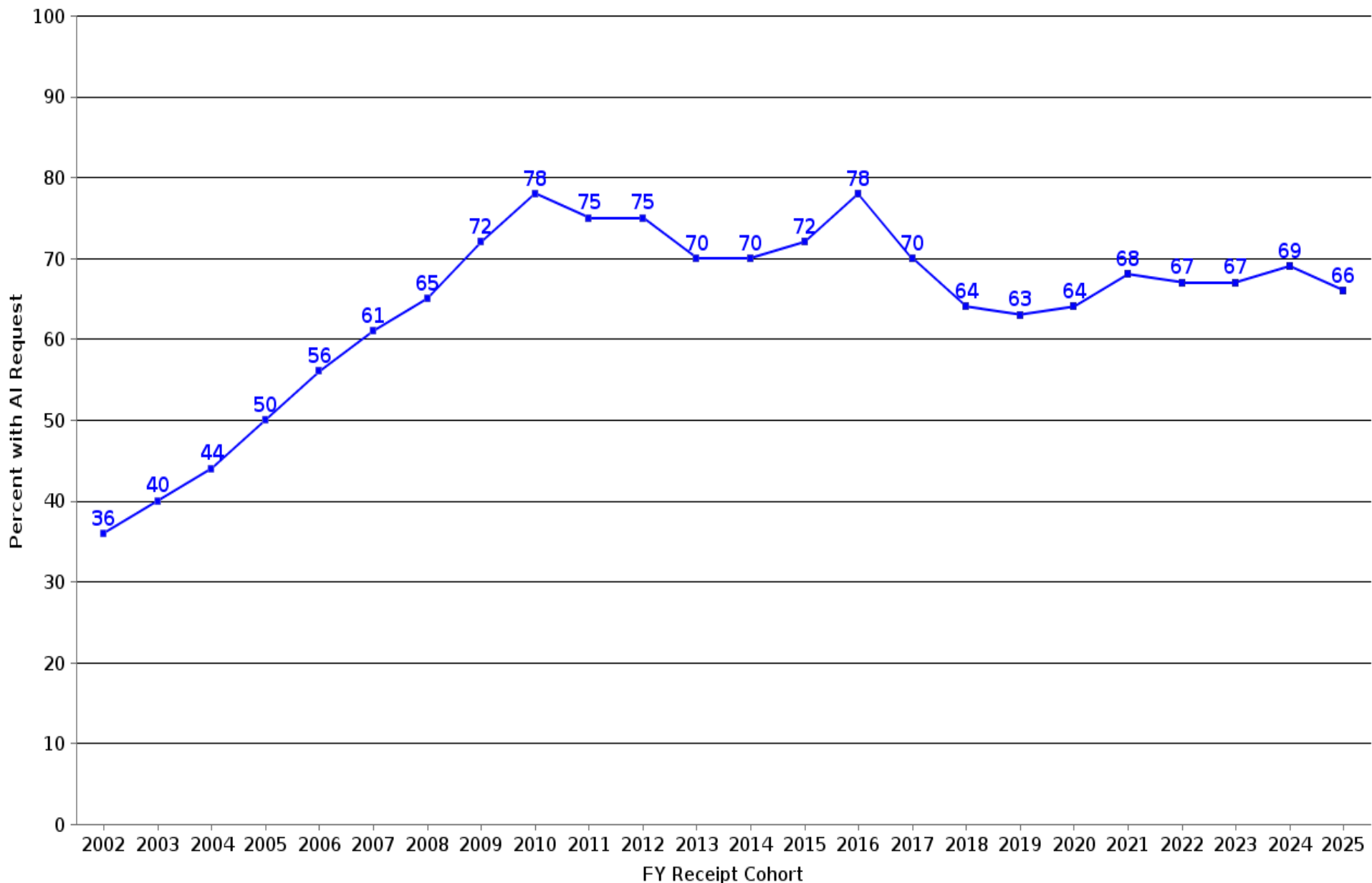


510(k)s

Q2FY2025



# Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle

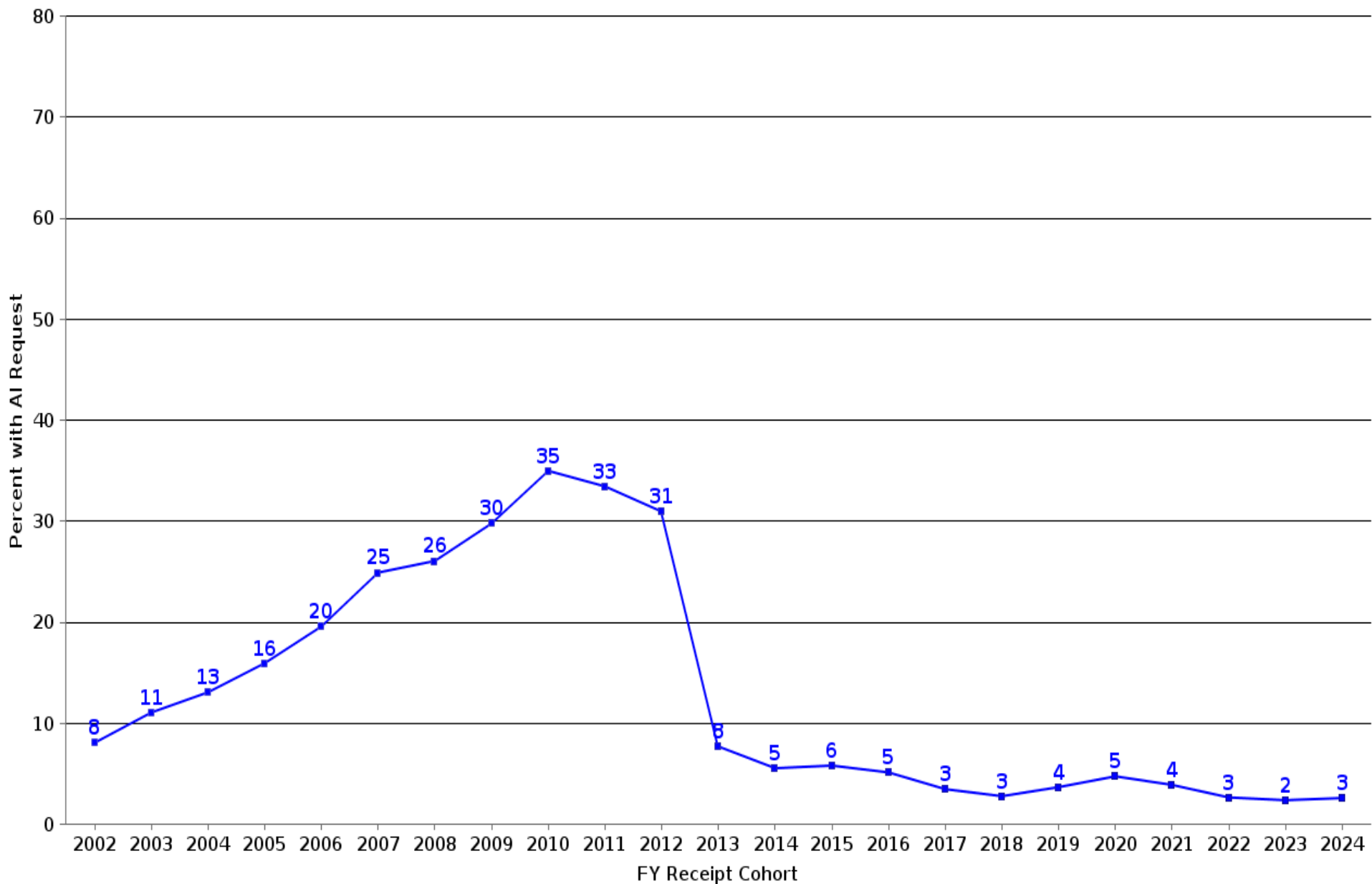


AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 1/31/25

■ % with 1st Cycle AI Request



# Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle

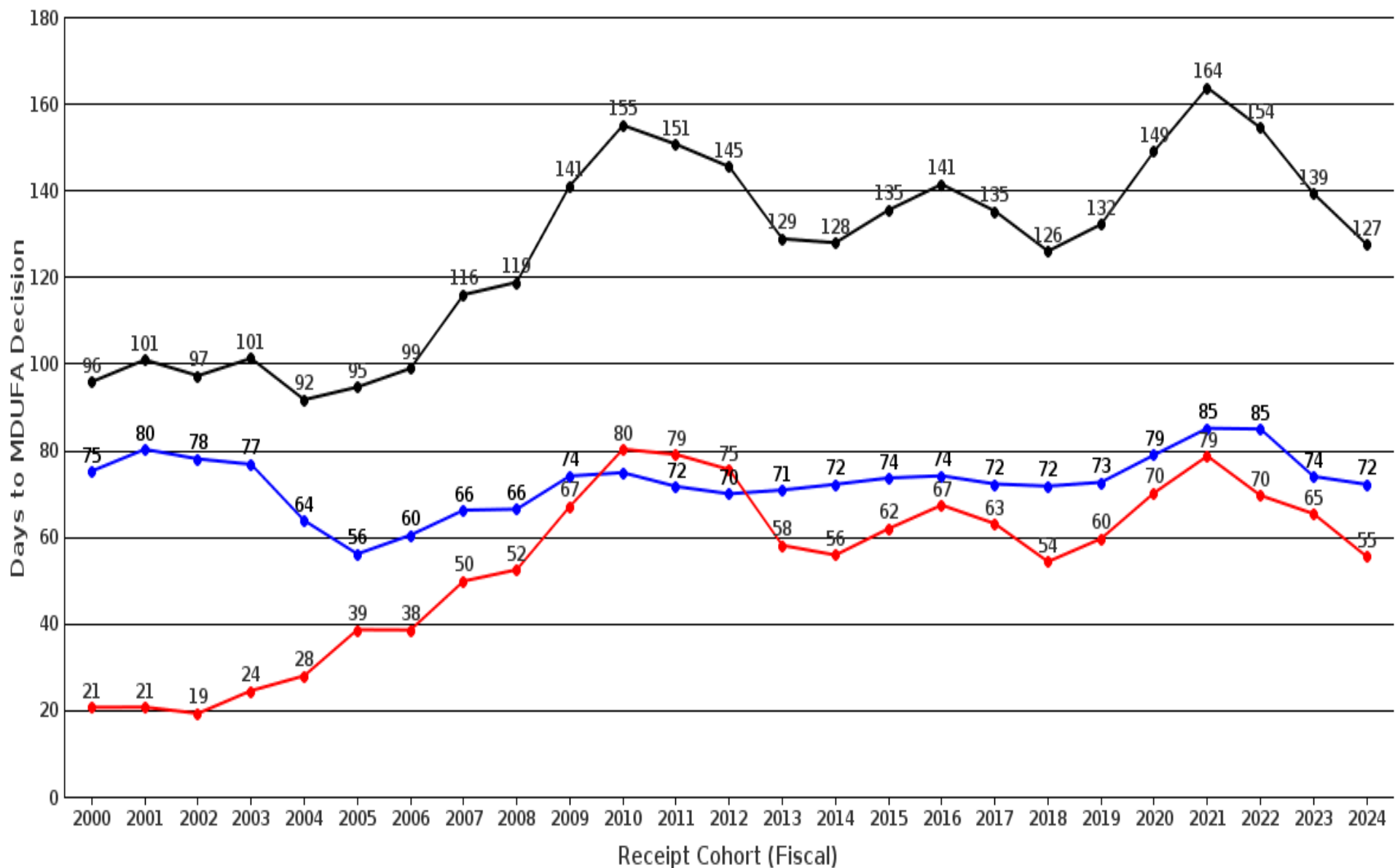


AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 8/31/24

■ % with 2nd Cycle AI Request



# 510(k) Avg Days to MDUFA Decision as of: 3/31/25



Cohorts not yet closed: 2021: 99.85%; 2022: 99.94%; 2023: 99.61%; 2024: 86.53%

● Avg FDA Days to MDUFA Decision ● Avg Applicant Days to MDUFA Decision ● Avg Total Elapsed Days to MDUFA Decision

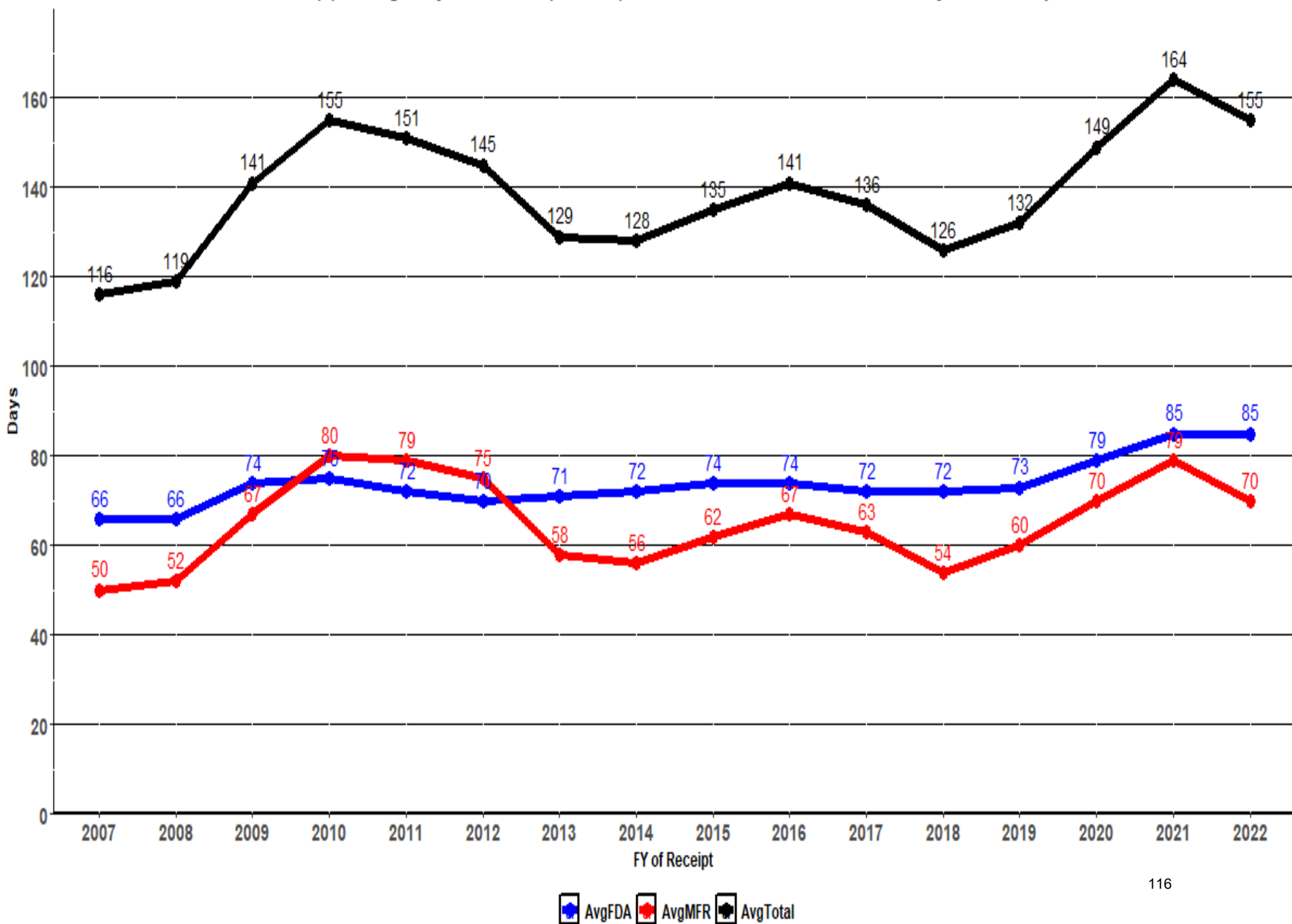


510(k) Average Days to MDUFA (SE/NSE) Decision at 99.85 % Cohort Closure by FY of Receipt



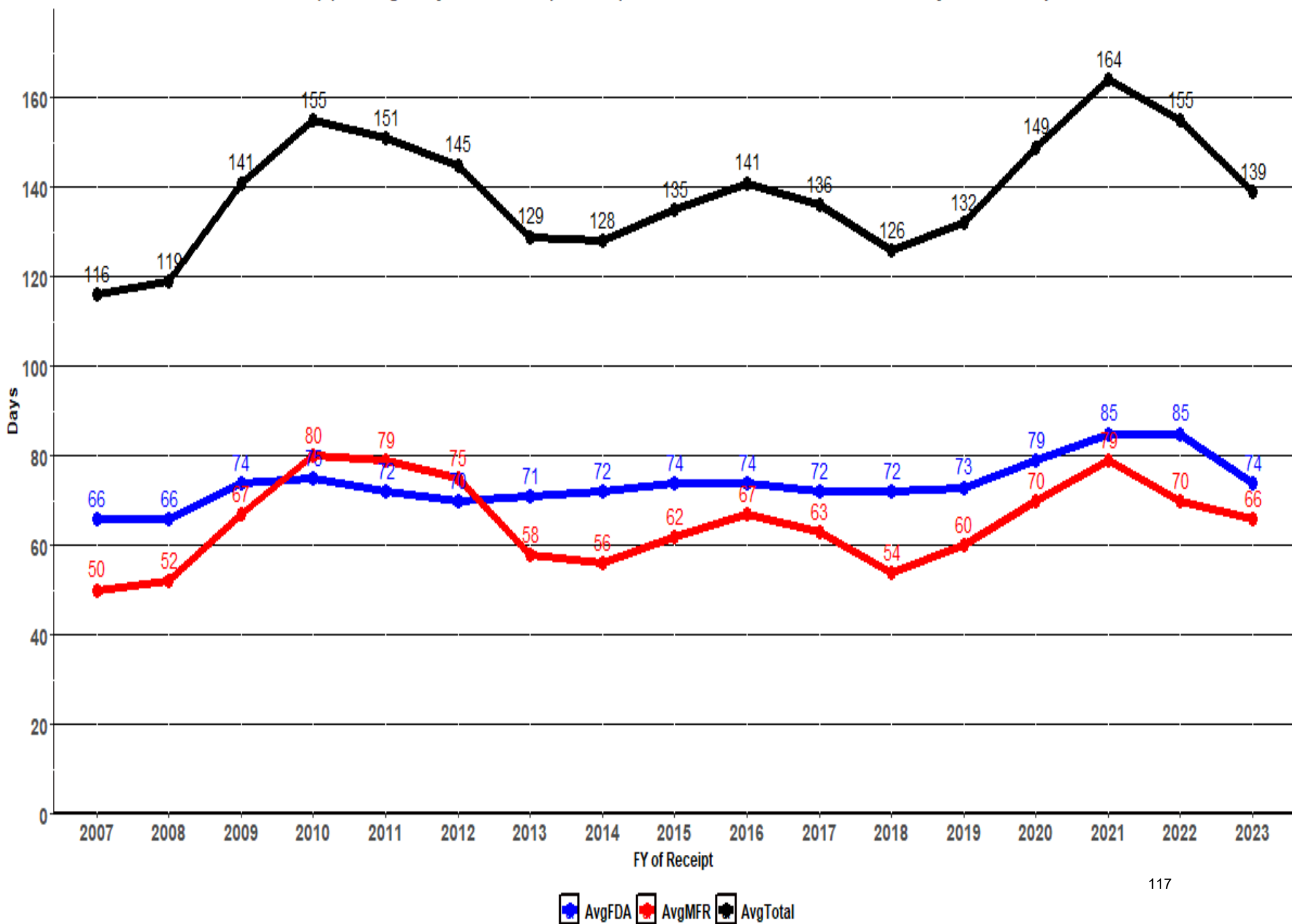


510(k) Average Days to MDUFA (SE/NSE) Decision at 99.94 % Cohort Closure by FY of Receipt



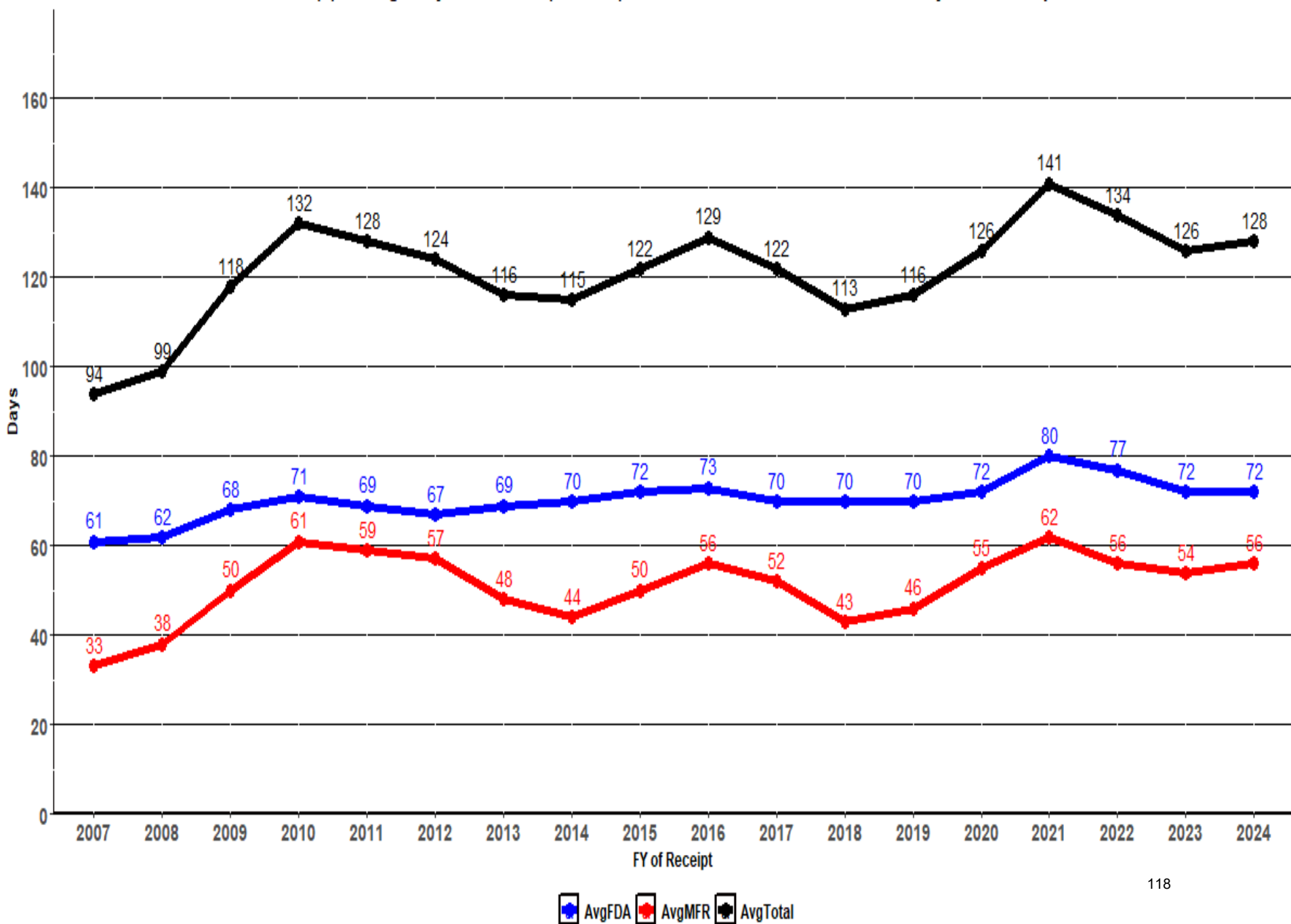


510(k) Average Days to MDUFA (SE/NSE) Decision at 99.61 % Cohort Closure by FY of Receipt





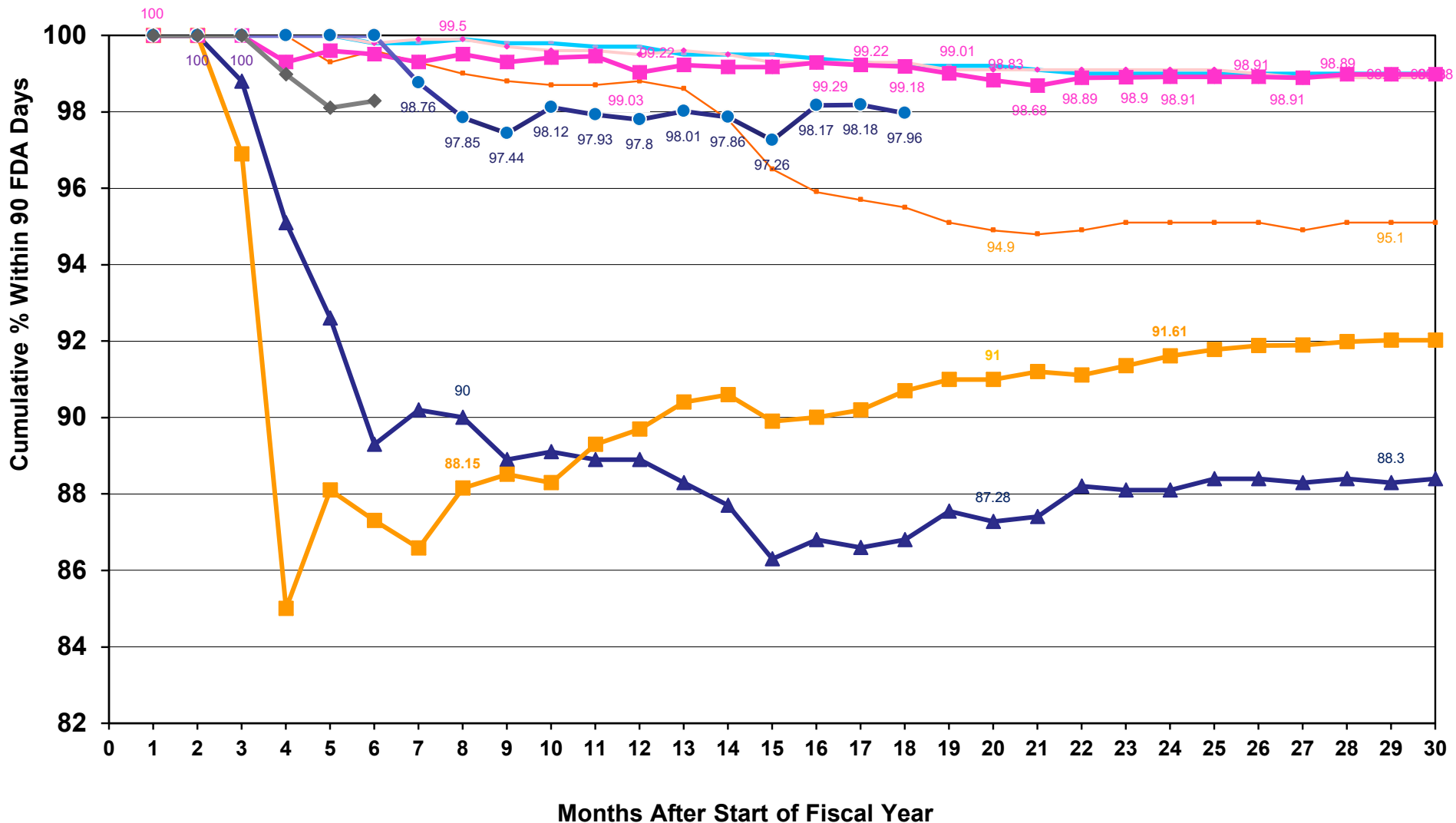
510(k) Average Days to MDUFA (SE/NSE) Decision at 86.53 % Cohort Closure by FY of Receipt





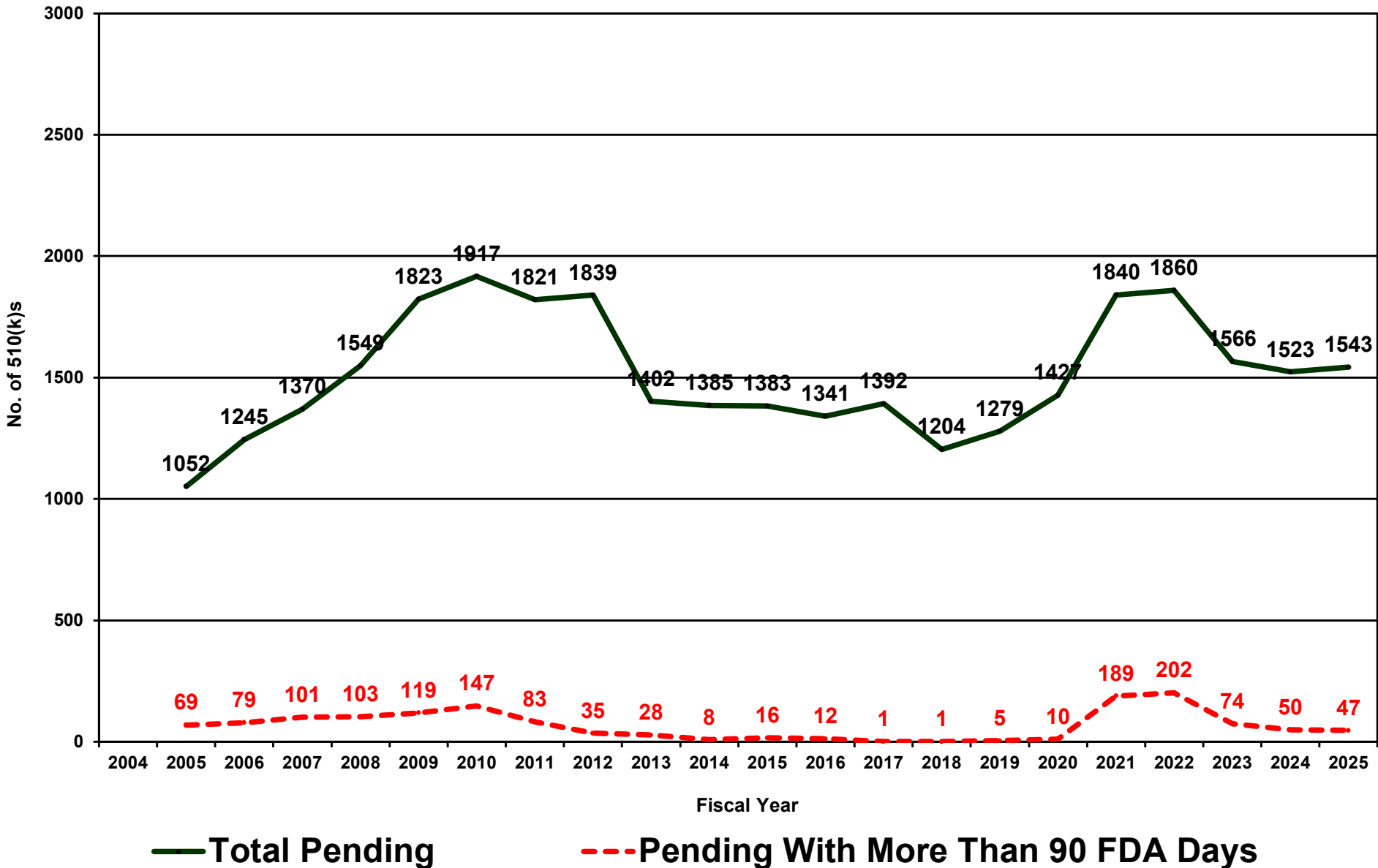
# Trend in 510(k) MDUFA Decision Goal Performance

## Comparison of FY18 – FY25 Receipt Cohorts





# 510(k)s Pending at End of Quarter/Year



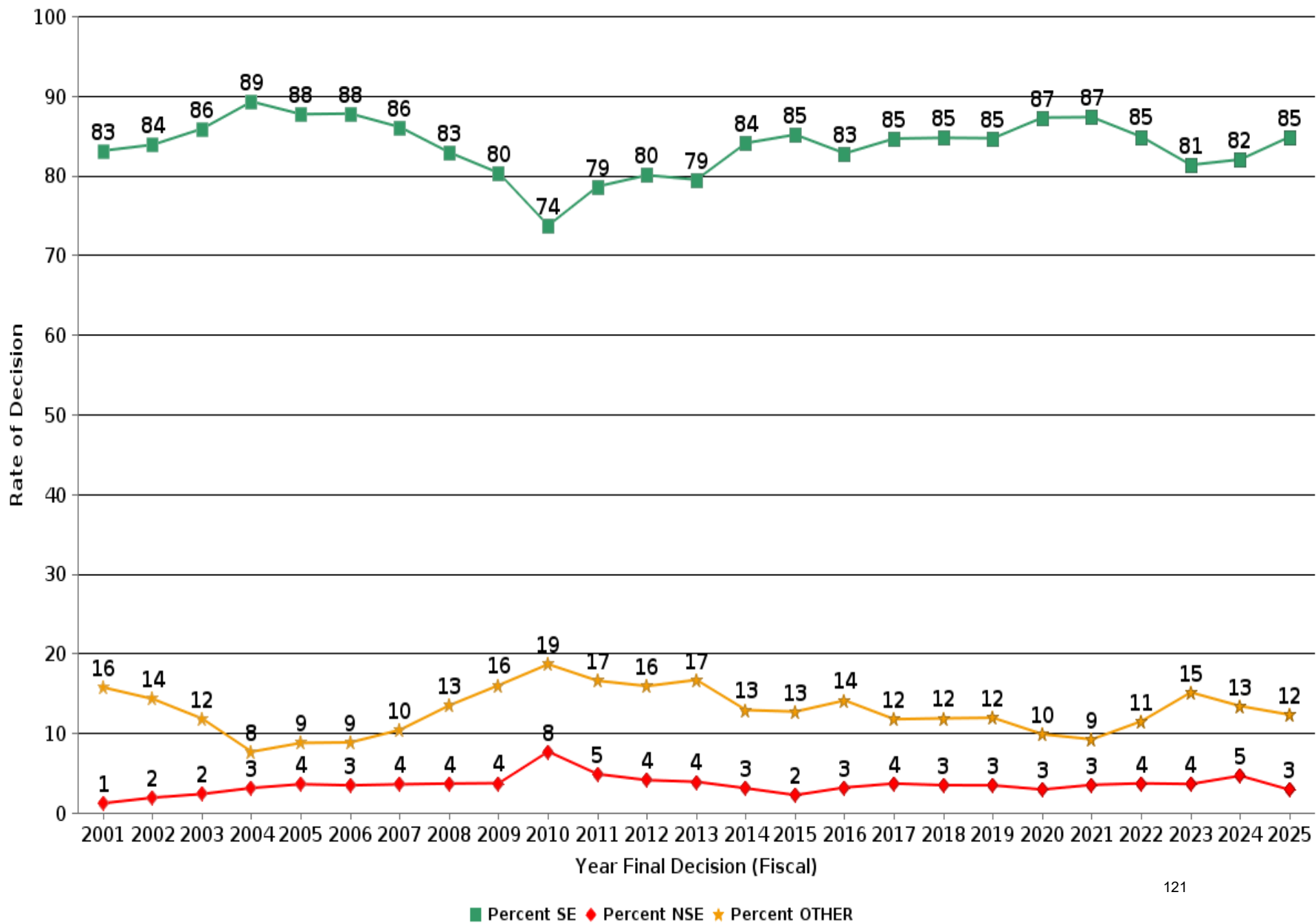
— Total Pending

- - - Pending With More Than 90 FDA Days

“Pending” means 510ks under review or on hold following a positive RTA decision (FY13 and later).



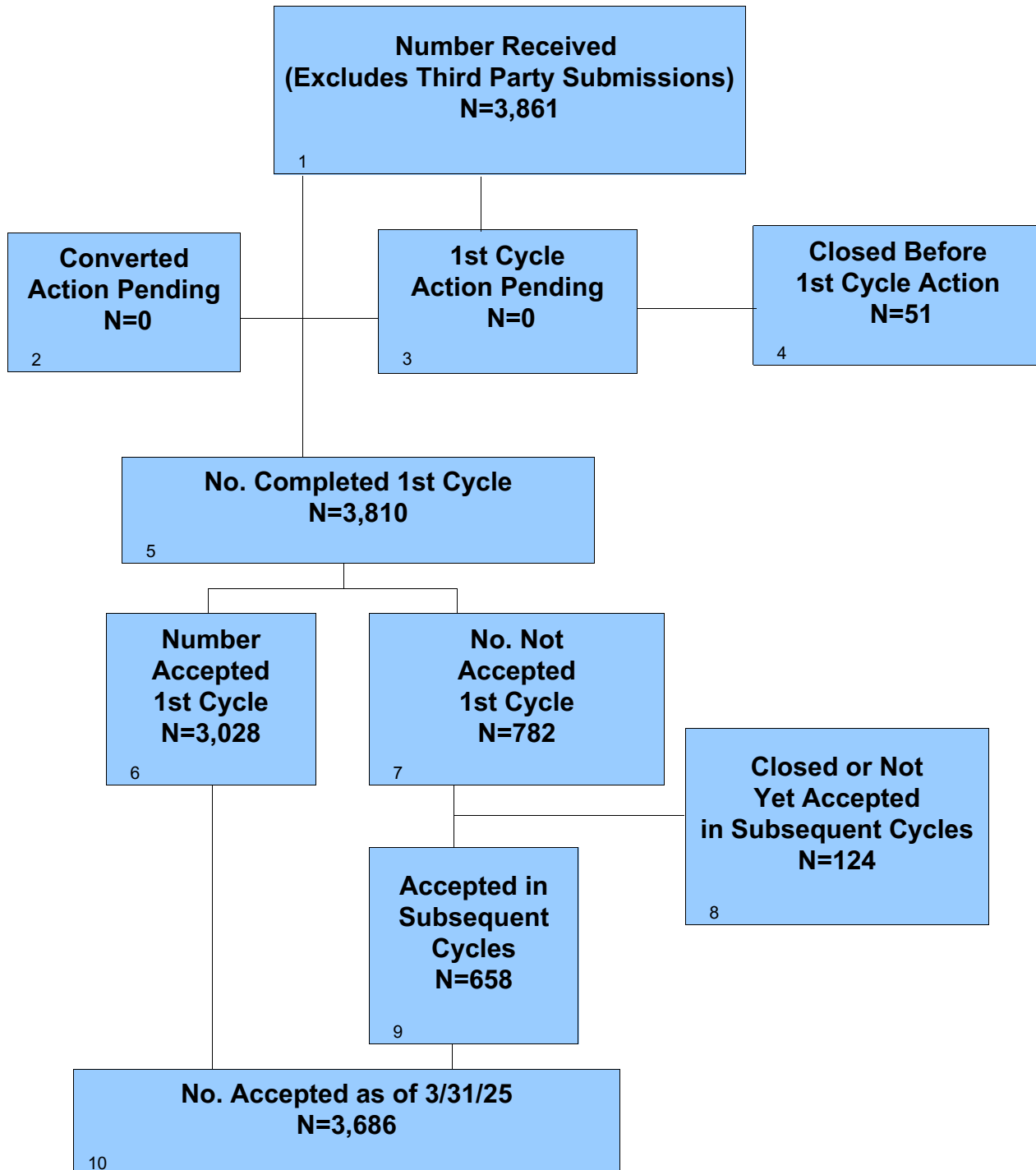
# Rates of SE, NSE and Other Decisions by FY of Decision





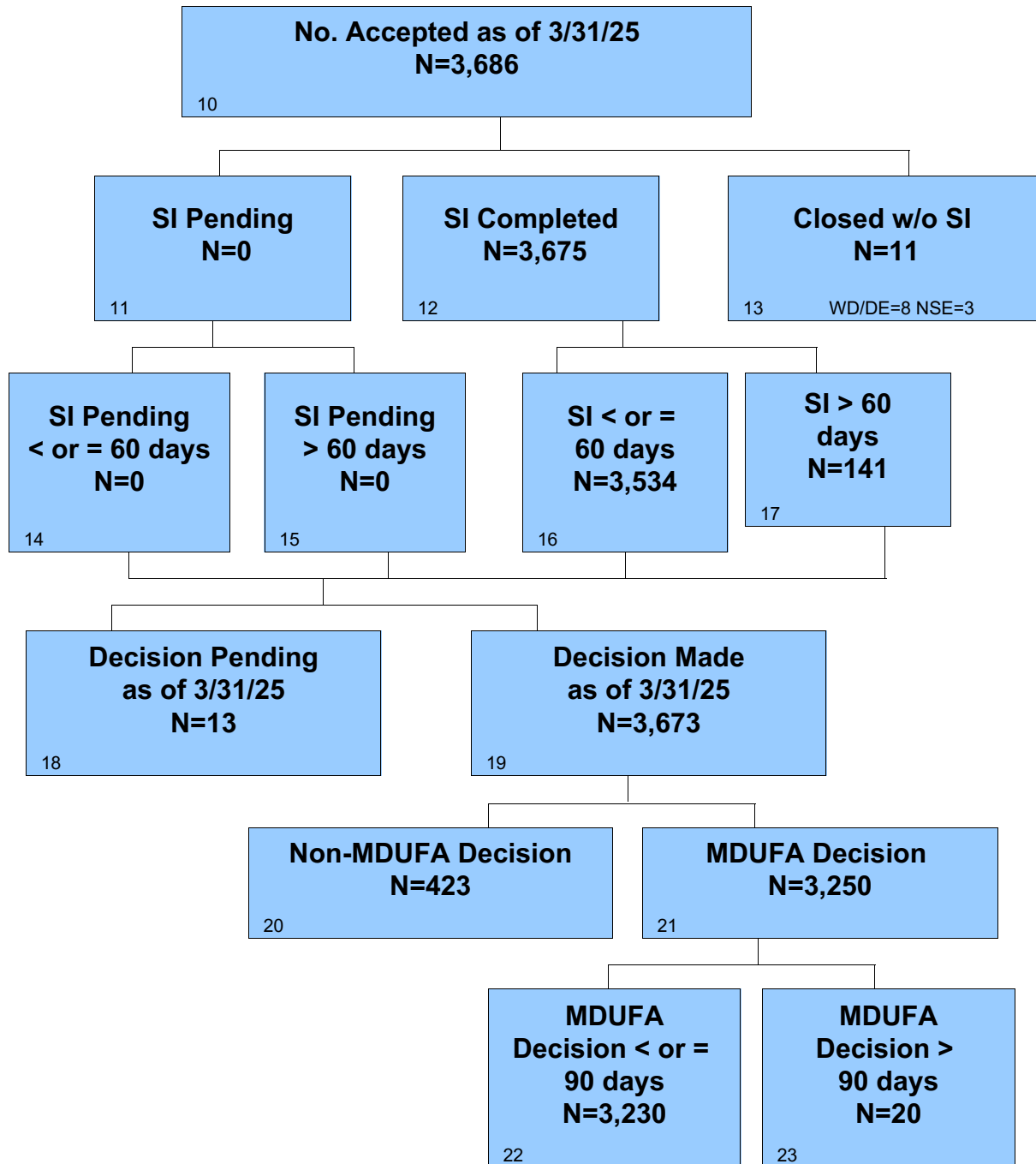
# CDRH 510(k)s - FY 2023 as of 3/31/25

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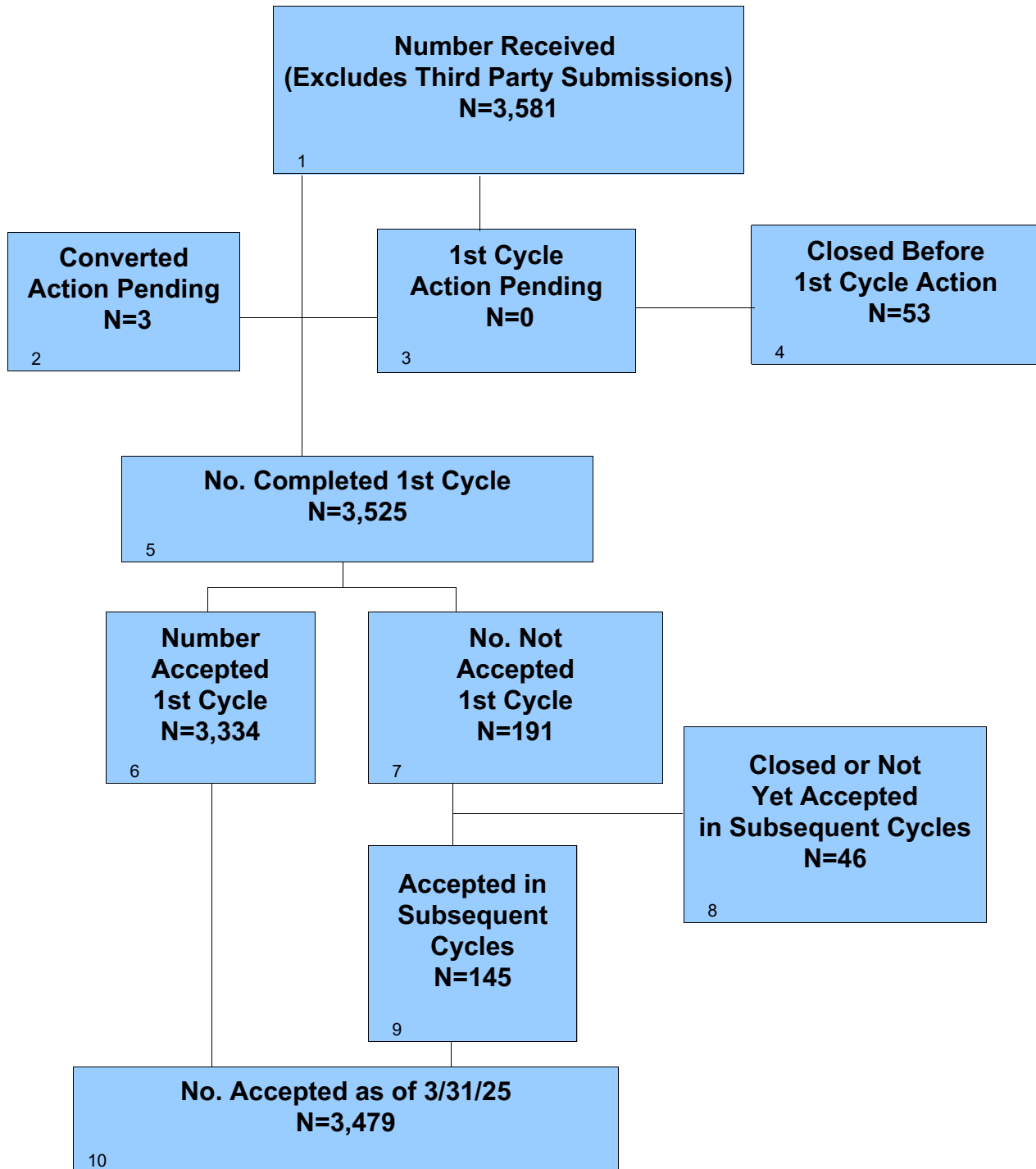
# CDRH 510(k)s - FY 2023 as of 3/31/25 Continued





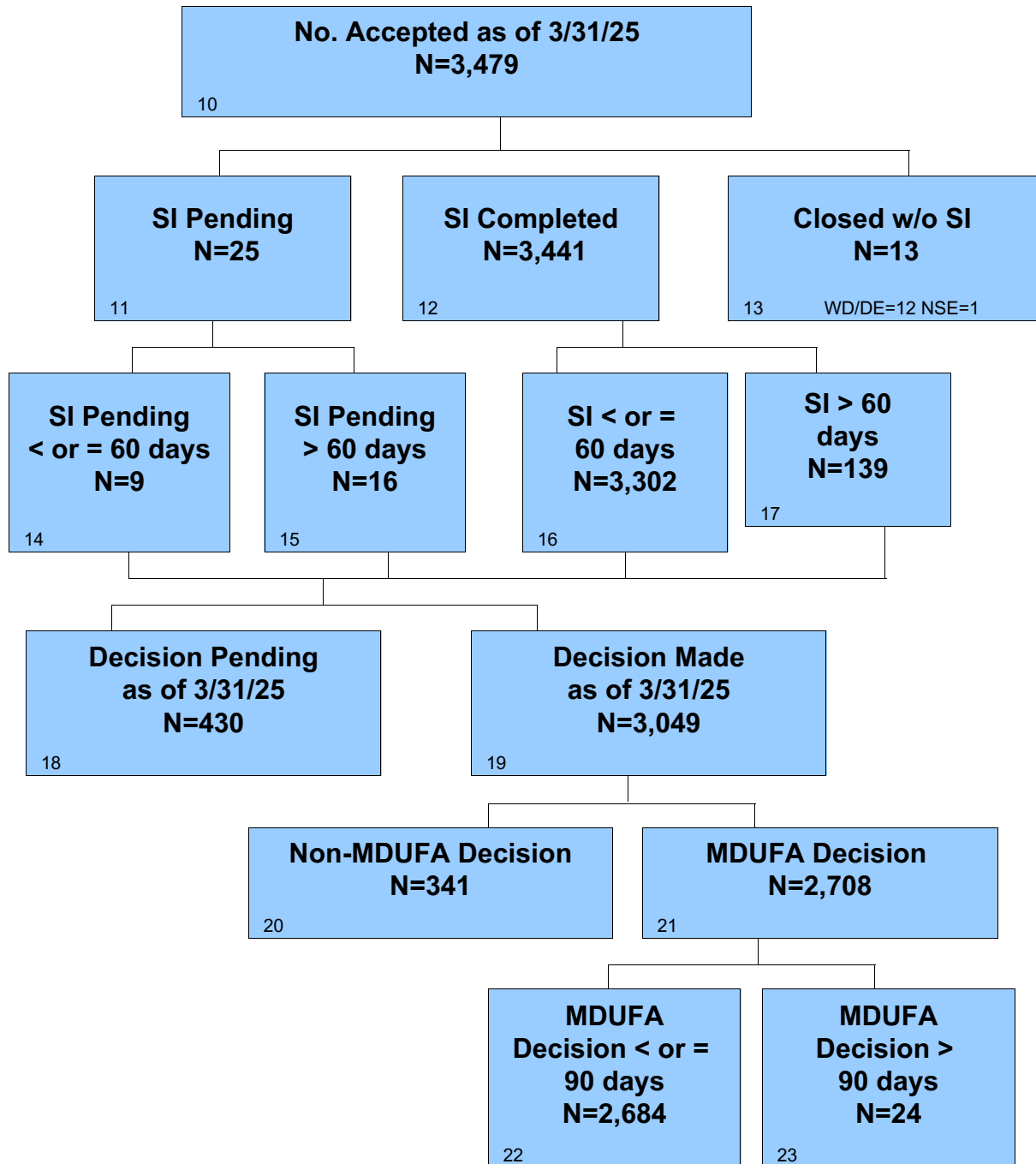
# CDRH 510(k)s - FY 2024 as of 3/31/25

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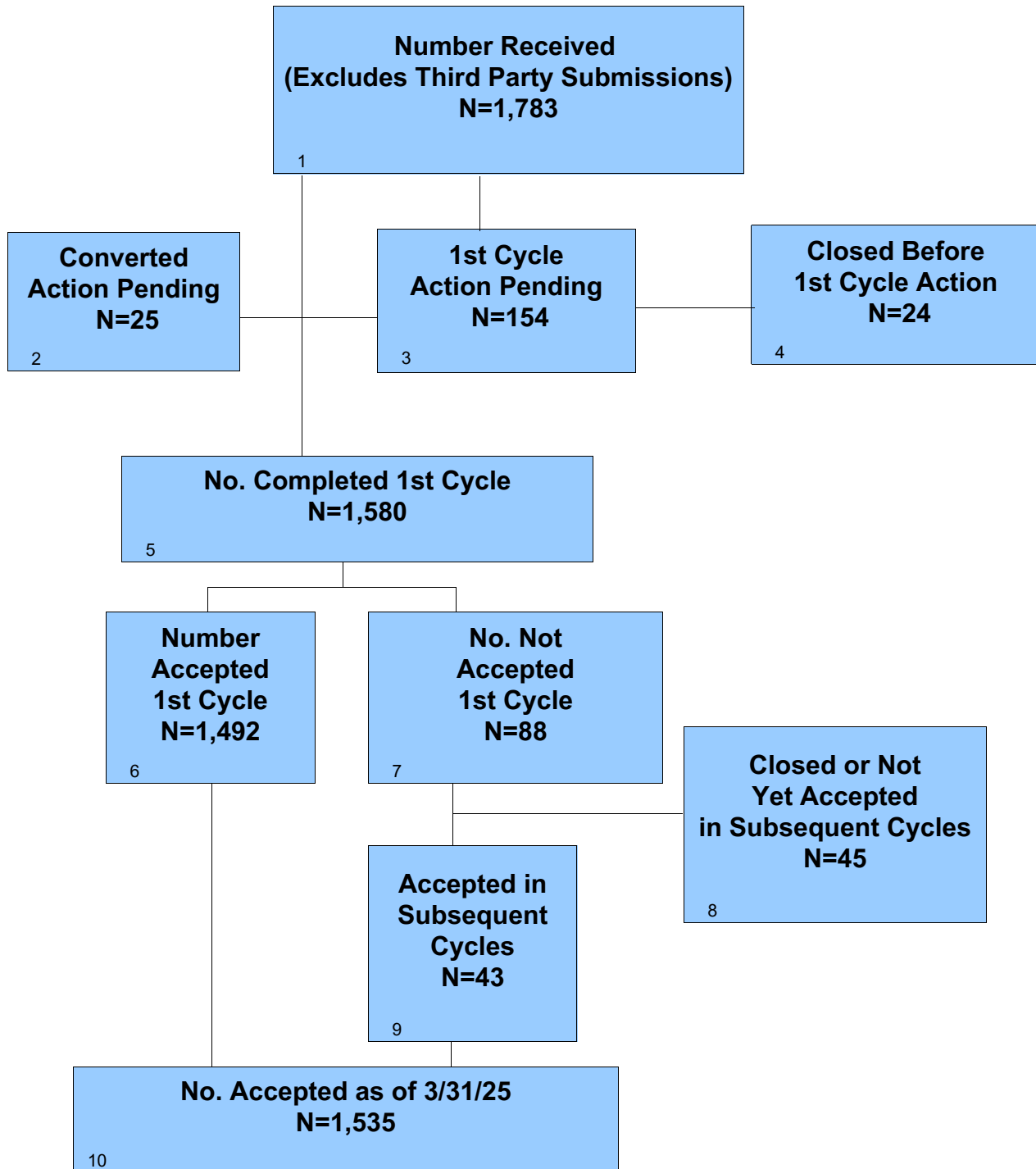
# CDRH 510(k)s - FY 2024 as of 3/31/25 Continued





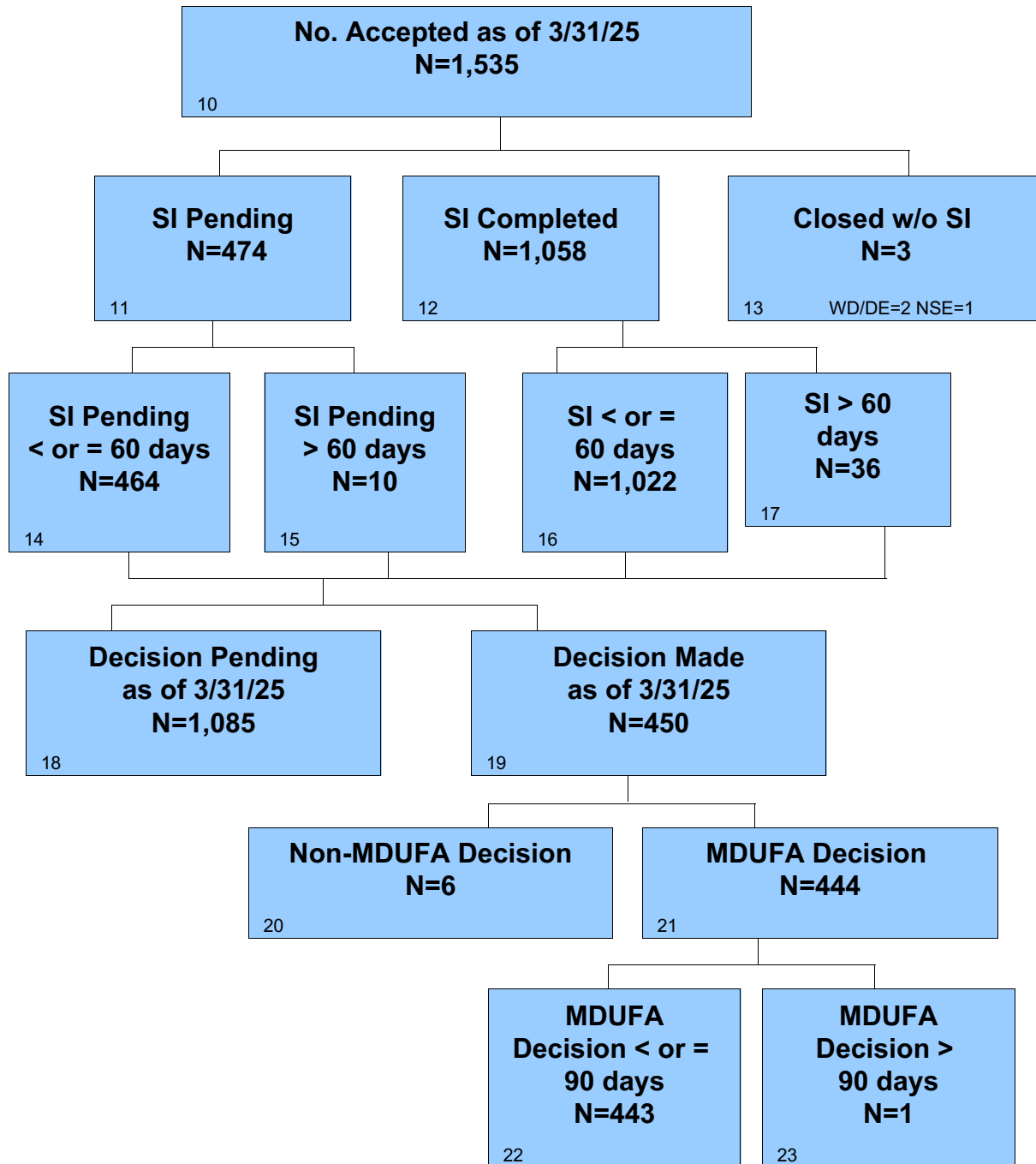
# CDRH 510(k)s - FY 2025 as of 3/31/25

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# CDRH 510(k)s - FY 2025 as of 3/31/25 Continued





## Section 6 510(k) Center Level Metrics (Excludes Third Party Review)

**Table 6.1 CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3,861	3,581	1,783		
Closed Before First RTA or TS Action <sup>1</sup>	51	53	24		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	3,010	3,305	1,469		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	18	29	23		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	3	179		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	782	191	88		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	20.52%	5.42%	5.57%		

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

**Table 6.2 CDRH - 510(k) Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible for SI	3,686	3,479	1,535		
Deleted or Withdrawn Prior to SI	8	12	2		
SI Within 60 FDA Days	3,534	3,302	1,022		
SI Over 60 FDA Days	141	139	36		
SI Pending Within 60 FDA Days	0	9	464		
SI Pending Over 60 FDA Days	0	16	10		
510(k)s NSE Without SI	3	1	1		
Current SI Performance Percent Within 60 FDA Days	96.08%	95.49%	95.60%		



**Table 6.3 CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interaction	3,675	3,441	1,058		
Average Number of FDA Days to Substantive Interaction	52.72	52.46	50.78		
20th Percentile FDA Days to Substantive Interaction	48	48	37		
40th Percentile FDA Days to Substantive Interaction	57	57	56		
60th Percentile FDA Days to Substantive Interaction	59	59	58		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	212	95	88		

**Table 6.4 CDRH - 510(k) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 95% Within 90 FDA Days</b>	<b>FY 2024 95% Within 90 FDA Days</b>	<b>FY 2025 95% Within 90 FDA Days</b>	<b>FY 2026 95% Within 90 FDA Days</b>	<b>FY 2027 95% Within 90 FDA Days</b>
510(k)s Accepted	3,686	3,479	1,535		
Non-MDUFA V Decision	423	341	6		
MDUFA V Decision (SE/NSE)	3,250	2,708	444		
MDUFA V Decision Within 90 FDA Days	3,230	2,684	443		
510(k)s Pending MDUFA V Decision	13	430	1,085		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	6	27	6		
Current Performance Percent Within 90 FDA Days	99.20%	98.14%	98.44%		



**Table 6.5 CDRH - 510(k) Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Average Review Cycles	1.67	1.64	1.23		
Number With MDUFA V Decision	3250	2708	444		
<b>Average Number of FDA Days to MDUFA V Decision</b>	74.82	73.06	55.56		
20th Percentile FDA Days to MDUFA V Decision	57	55	28		
40th Percentile FDA Days to MDUFA V Decision	84	83	47		
60th Percentile FDA Days to MDUFA V Decision	88	88	61		
80th Percentile FDA Days to MDUFA V Decision	90	90	87		
Maximum FDA Days to MDUFA V Decision	276	203	91		
<b>Average Number of Industry Days to MDUFA V Decision</b>	66.12	56.19	6.25		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	14	8	0		
60th Percentile Industry Days to MDUFA V Decision	69	51	0		
80th Percentile Industry Days to MDUFA V Decision	151	125	5		
Maximum Industry Days to MDUFA V Decision	367	361	86		
<b>Average Number of Total Days to MDUFA V Decision</b>	141.01	129.33	61.81		
20th Percentile Total Days to MDUFA V Decision	59	57	28		
40th Percentile Total Days to MDUFA V Decision	97	90	50		
60th Percentile Total Days to MDUFA V Decision	155	136	72		
80th Percentile Total Days to MDUFA V Decision	237	210	90		
Maximum Total Days to MDUFA V Decision	517	451	171		



**Table 6.6 CDRH - 510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	3,686	3,479	1,535		
Number With MDUFA V Decision	3,250	2,708	444		
Number of SE Decision	3,106	2,612	442		
Number of NSE Decision	144	96	2		
Number of Withdrawal	223	195	4		
Number of Deleted	192	139	0		
Rate of SE Decision	95.57%	96.45%	99.55%		
Rate of NSE Decision	4.43%	3.55%	0.45%		
Rate of Withdrawal	6.05%	5.61%	0.26%		
Rate of Deleted	5.21%	4.00%	0.00%		

**Table 6.7 CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	20	24	1		
Mean FDA Days for Submissions that Missed the Goal	124.45	102.83	91.00		
Mean Industry Days for Submissions that Missed the Goal	129.15	127.88	0.00		

**Table 6.8 CDRH - LDT 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	2	4	0		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision (SE/NSE)	2	3	0		
MDUFA V Decision Within 90 FDA Days	2	3	0		
510(k)s Pending MDUFA V Decision	0	1	0		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	N/A		

**Table 6.9 CDRH - Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	269	235	122		
Non-MDUFA V Decision	51	38	0		
MDUFA V Decision (SE/NSE)	218	164	45		
MDUFA V Decision Within 90 FDA Days	218	164	45		
510(k)s Pending MDUFA V Decision	0	33	77		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%		



## Section 6 510(k) Office Level Metric (Excludes Third Party Review)

**Table 6.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
510(k) Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	577	537	255		
Closed Before First RTA or TS Action <sup>1</sup>	8	8	3		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	313	471	208		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	3	4	1		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	1	27		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	253	53	16		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	44.46%	10.04%	7.11%		

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

**Table 6.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
510(k) Substantive Interaction (SI) Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	532	517	214		
Deleted or Withdrawn Prior to SI	2	2	1		
SI Within 60 FDA Days	424	426	136		
SI Over 60 FDA Days	105	84	3		
SI Pending Within 60 FDA Days	0	1	71		
SI Pending Over 60 FDA Days	0	4	3		
510(k)s NSE Without SI	1	0	0		
Current SI Performance Percent Within 60 FDA Days	80.00%	82.88%	95.77%		



**Table 6.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interaction	529	510	139		
Average Number of FDA Days to Substantive Interaction	56.96	55.80	54.19		
20th Percentile FDA Days to Substantive Interaction	55	53	50		
40th Percentile FDA Days to Substantive Interaction	58	57	57		
60th Percentile FDA Days to Substantive Interaction	60	59	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	212	80	65		

**Table 6.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
510(k) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 95% Within 90 FDA Days</b>	<b>FY 2024 95% Within 90 FDA Days</b>	<b>FY 2025 95% Within 90 FDA Days</b>	<b>FY 2026 95% Within 90 FDA Days</b>	<b>FY 2027 95% Within 90 FDA Days</b>
510(k)s Accepted	532	517	214		
Non-MDUFA V Decision	81	49	2		
MDUFA V Decision (SE/NSE)	446	382	27		
MDUFA V Decision Within 90 FDA Days	437	377	27		
510(k)s Pending MDUFA V Decision	5	86	185		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	1	5	1		
Current Performance Percent Within 90 FDA Days	97.76%	97.42%	96.43%		



**Table 6.5 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
510(k) Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Average Review Cycles	1.76	1.73	1.52		
Number With MDUFA V Decision	446	382	27		
<b>Average Number of FDA Days to MDUFA V Decision</b>	82.90	81.31	64.48		
20th Percentile FDA Days to MDUFA V Decision	82	80	33		
40th Percentile FDA Days to MDUFA V Decision	88	87	60		
60th Percentile FDA Days to MDUFA V Decision	89	89	84		
80th Percentile FDA Days to MDUFA V Decision	90	90	89		
Maximum FDA Days to MDUFA V Decision	276	120	90		
<b>Average Number of Industry Days to MDUFA V Decision</b>	76.31	70.96	12.44		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	39	28	0		
60th Percentile Industry Days to MDUFA V Decision	87	77	8		
80th Percentile Industry Days to MDUFA V Decision	162	154	21		
Maximum Industry Days to MDUFA V Decision	353	356	54		
<b>Average Number of Total Days to MDUFA V Decision</b>	159.37	152.27	76.93		
20th Percentile Total Days to MDUFA V Decision	87	87	44		
40th Percentile Total Days to MDUFA V Decision	126	115	60		
60th Percentile Total Days to MDUFA V Decision	178	165	90		
80th Percentile Total Days to MDUFA V Decision	251	240	108		
Maximum Total Days to MDUFA V Decision	443	451	136		



**Table 6.6 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	532	517	214		
Number With MDUFA V Decision	446	382	27		
Number of SE Decision	411	363	27		
Number of NSE Decision	35	19	0		
Number of Withdrawal	40	24	1		
Number of Deleted	40	24	0		
Rate of SE Decision	92.15%	95.03%	100.00%		
Rate of NSE Decision	7.85%	4.97%	0.00%		
Rate of Withdrawal	7.52%	4.64%	0.47%		
Rate of Deleted	7.52%	4.64%	0.00%		

**Table 6.7 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
510(k) Performance Metric - Submission Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	9	5	0		
Mean FDA Days for Submissions that Missed the Goal	148.78	104.20	N/A		
Mean Industry Days for Submissions that Missed the Goal	120.78	163.40	N/A		

**Table 6.8 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
LDT 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		

**Table 6.9 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		



**Table 6.1 OHT2 - Office of Cardiovascular Devices**  
**510(k) Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	380	383	180		
Closed Before First RTA or TS Action <sup>1</sup>	8	6	5		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	333	359	132		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	1	6	5		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	0	18		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	38	12	20		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	10.22%	3.18%	12.74%		

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

**Table 6.2 OHT2 - Office of Cardiovascular Devices**  
**510(k) Substantive Interaction (SI) Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	366	375	147		
Deleted or Withdrawn Prior to SI	0	0	0		
SI Within 60 FDA Days	356	347	78		
SI Over 60 FDA Days	10	22	11		
SI Pending Within 60 FDA Days	0	0	55		
SI Pending Over 60 FDA Days	0	6	2		
510(k)s NSE Without SI	0	0	1		
Current SI Performance Percent Within 60 FDA Days	97.27%	92.53%	84.78%		



**Table 6.3 OHT2 - Office of Cardiovascular Devices**

**510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interaction	366	369	89		
Average Number of FDA Days to Substantive Interaction	51.42	51.13	51.29		
20th Percentile FDA Days to Substantive Interaction	44	30	30		
40th Percentile FDA Days to Substantive Interaction	56	56	57		
60th Percentile FDA Days to Substantive Interaction	59	59	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	86	85	83		

**Table 6.4 OHT2 - Office of Cardiovascular Devices**

**510(k) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 95% Within 90 FDA Days</b>	<b>FY 2024 95% Within 90 FDA Days</b>	<b>FY 2025 95% Within 90 FDA Days</b>	<b>FY 2026 95% Within 90 FDA Days</b>	<b>FY 2027 95% Within 90 FDA Days</b>
510(k)s Accepted	366	375	147		
Non-MDUFA V Decision	34	38	0		
MDUFA V Decision (SE/NSE)	331	288	29		
MDUFA V Decision Within 90 FDA Days	327	283	29		
510(k)s Pending MDUFA V Decision	1	49	118		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	1	8	2		
Current Performance Percent Within 90 FDA Days	98.49%	95.61%	93.55%		



**Table 6.5 OHT2 - Office of Cardiovascular Devices**  
**510(k) Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Average Review Cycles	1.72	1.71	1.21		
Number With MDUFA V Decision	331	288	29		
<b>Average Number of FDA Days to MDUFA V Decision</b>	73.39	70.61	51.72		
20th Percentile FDA Days to MDUFA V Decision	55	50	30		
40th Percentile FDA Days to MDUFA V Decision	84	69	30		
60th Percentile FDA Days to MDUFA V Decision	88	88	58		
80th Percentile FDA Days to MDUFA V Decision	90	90	82		
Maximum FDA Days to MDUFA V Decision	95	203	89		
<b>Average Number of Industry Days to MDUFA V Decision</b>	71.75	64.42	4.90		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	27	22	0		
60th Percentile Industry Days to MDUFA V Decision	78	65	0		
80th Percentile Industry Days to MDUFA V Decision	155	138	0		
Maximum Industry Days to MDUFA V Decision	360	210	34		
<b>Average Number of Total Days to MDUFA V Decision</b>	145.14	135.03	56.62		
20th Percentile Total Days to MDUFA V Decision	57	52	30		
40th Percentile Total Days to MDUFA V Decision	107	104	30		
60th Percentile Total Days to MDUFA V Decision	162	152	62		
80th Percentile Total Days to MDUFA V Decision	238	228	86		
Maximum Total Days to MDUFA V Decision	448	327	120		



**Table 6.6 OHT2 - Office of Cardiovascular Devices**

**510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	366	375	147		
Number With MDUFA V Decision	331	288	29		
Number of SE Decision	308	272	27		
Number of NSE Decision	23	16	2		
Number of Withdrawal	17	24	0		
Number of Deleted	17	12	0		
Rate of SE Decision	93.05%	94.44%	93.10%		
Rate of NSE Decision	6.95%	5.56%	6.90%		
Rate of Withdrawal	4.64%	6.40%	0.00%		
Rate of Deleted	4.64%	3.20%	0.00%		

**Table 6.7 OHT2 - Office of Cardiovascular Devices**

**510(k) Performance Metric - Submission Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	4	5	0		
Mean FDA Days for Submissions that Missed the Goal	92.75	118.60	N/A		
Mean Industry Days for Submissions that Missed the Goal	82.50	113.20	N/A		

**Table 6.8 OHT2 - Office of Cardiovascular Devices**

**LDT 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		

**Table 6.9 OHT2 - Office of Cardiovascular Devices**

**Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		



**Table 6.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
510(k) Acceptance Review Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	480	454	237		
Closed Before First RTA or TS Action <sup>1</sup>	5	11	2		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	391	425	203		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	2	2	4		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	0	21		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	82	16	7		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	17.26%	3.61%	3.27%		

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

**Table 6.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
510(k) Substantive Interaction (SI) Performance Goal**

<b>Substantive Interaction (SI) Goal</b>	<b>FY 2023 95% SI Within 60 FDA Days</b>	<b>FY 2024 95% SI Within 60 FDA Days</b>	<b>FY 2025 95% SI Within 60 FDA Days</b>	<b>FY 2026 95% SI Within 60 FDA Days</b>	<b>FY 2027 95% SI Within 60 FDA Days</b>
Eligible For SI	462	439	210		
Deleted or Withdrawn Prior to SI	1	0	0		
SI Within 60 FDA Days	451	436	125		
SI Over 60 FDA Days	10	0	5		
SI Pending Within 60 FDA Days	0	0	77		
SI Pending Over 60 FDA Days	0	2	3		
510(k)s NSE Without SI	0	1	0		
Current SI Performance Percent Within 60 FDA Days	97.83%	99.32%	93.98%		



**Table 6.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interaction	461	436	130		
Average Number of FDA Days to Substantive Interaction	54.95	52.98	50.48		
20th Percentile FDA Days to Substantive Interaction	55	49	30		
40th Percentile FDA Days to Substantive Interaction	58	57	55		
60th Percentile FDA Days to Substantive Interaction	59	59	58		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	77	60	88		

**Table 6.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**510(k) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 95% Within 90 FDA Days</b>	<b>FY 2024 95% Within 90 FDA Days</b>	<b>FY 2025 95% Within 90 FDA Days</b>	<b>FY 2026 95% Within 90 FDA Days</b>	<b>FY 2027 95% Within 90 FDA Days</b>
510(k)s Accepted	462	439	210		
Non-MDUFA V Decision	54	52	0		
MDUFA V Decision (SE/NSE)	405	310	47		
MDUFA V Decision Within 90 FDA Days	404	309	47		
510(k)s Pending MDUFA V Decision	3	77	163		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	3	8	1		
Current Performance Percent Within 90 FDA Days	99.02%	97.17%	97.92%		



**Table 6.5 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**510(k) Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Average Review Cycles	1.78	1.73	1.30		
Number With MDUFA V Decision	405	310	47		
<b>Average Number of FDA Days to MDUFA V Decision</b>	79.93	74.45	52.13		
20th Percentile FDA Days to MDUFA V Decision	79	57	28		
40th Percentile FDA Days to MDUFA V Decision	88	86	30		
60th Percentile FDA Days to MDUFA V Decision	89	88	58		
80th Percentile FDA Days to MDUFA V Decision	90	90	88		
Maximum FDA Days to MDUFA V Decision	93	91	90		
<b>Average Number of Industry Days to MDUFA V Decision</b>	85.37	66.87	9.87		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	48	25	0		
60th Percentile Industry Days to MDUFA V Decision	106	73	0		
80th Percentile Industry Days to MDUFA V Decision	172	139	20		
Maximum Industry Days to MDUFA V Decision	354	216	85		
<b>Average Number of Total Days to MDUFA V Decision</b>	165.30	141.44	62.00		
20th Percentile Total Days to MDUFA V Decision	87	59	28		
40th Percentile Total Days to MDUFA V Decision	133	110	30		
60th Percentile Total Days to MDUFA V Decision	193	160	60		
80th Percentile Total Days to MDUFA V Decision	260	226	102		
Maximum Total Days to MDUFA V Decision	443	306	171		



**Table 6.6 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	462	439	210		
Number With MDUFA V Decision	405	310	47		
Number of SE Decision	379	290	47		
Number of NSE Decision	26	20	0		
Number of Withdrawal	24	30	0		
Number of Deleted	29	20	0		
Rate of SE Decision	93.58%	93.55%	100.00%		
Rate of NSE Decision	6.42%	6.45%	0.00%		
Rate of Withdrawal	5.19%	6.83%	0.00%		
Rate of Deleted	6.28%	4.56%	0.00%		

**Table 6.7 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**510(k) Performance Metric - Submission Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	1	0		
Mean FDA Days for Submissions that Missed the Goal	93.00	91.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	192.00	42.00	N/A		

**Table 6.8 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**LDT 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		

**Table 6.9 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		



**Table 6.1 OHT4 - Office of Surgical and Infection Control Devices**  
**510(k) Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	708	619	283		
Closed Before First RTA or TS Action <sup>1</sup>	10	6	3		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	558	566	222		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	1	12	10		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	0	30		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	139	35	18		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	19.91%	5.71%	7.20%		

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

**Table 6.2 OHT4 - Office of Surgical and Infection Control Devices**  
**510(k) Substantive Interaction (SI) Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	676	601	243		
Deleted or Withdrawn Prior to SI	1	5	0		
SI Within 60 FDA Days	670	579	151		
SI Over 60 FDA Days	5	12	10		
SI Pending Within 60 FDA Days	0	1	80		
SI Pending Over 60 FDA Days	0	4	2		
510(k)s NSE Without SI	0	0	0		
Current SI Performance Percent Within 60 FDA Days	99.26%	97.31%	92.64%		



**Table 6.3 OHT4 - Office of Surgical and Infection Control Devices**  
**510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interaction	675	591	161		
Average Number of FDA Days to Substantive Interaction	52.61	52.80	51.30		
20th Percentile FDA Days to Substantive Interaction	49	49	39		
40th Percentile FDA Days to Substantive Interaction	56	57	57		
60th Percentile FDA Days to Substantive Interaction	58	58	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	122	66	73		

**Table 6.4 OHT4 - Office of Surgical and Infection Control Devices**  
**510(k) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 95% Within 90 FDA Days</b>	<b>FY 2024 95% Within 90 FDA Days</b>	<b>FY 2025 95% Within 90 FDA Days</b>	<b>FY 2026 95% Within 90 FDA Days</b>	<b>FY 2027 95% Within 90 FDA Days</b>
510(k)s Accepted	676	601	243		
Non-MDUFA V Decision	88	69	2		
MDUFA V Decision (SE/NSE)	586	469	75		
MDUFA V Decision Within 90 FDA Days	584	464	74		
510(k)s Pending MDUFA V Decision	2	63	166		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	5	1		
Current Performance Percent Within 90 FDA Days	99.66%	97.89%	97.37%		



**Table 6.5 OHT4 - Office of Surgical and Infection Control Devices**  
**510(k) Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Average Review Cycles	1.62	1.55	1.23		
Number With MDUFA V Decision	586	469	75		
<b>Average Number of FDA Days to MDUFA V Decision</b>	75.09	73.23	58.79		
20th Percentile FDA Days to MDUFA V Decision	58	56	27		
40th Percentile FDA Days to MDUFA V Decision	83	83	57		
60th Percentile FDA Days to MDUFA V Decision	87	88	76		
80th Percentile FDA Days to MDUFA V Decision	89	90	88		
Maximum FDA Days to MDUFA V Decision	101	95	91		
<b>Average Number of Industry Days to MDUFA V Decision</b>	55.84	41.27	6.41		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	0	0		
60th Percentile Industry Days to MDUFA V Decision	46	29	0		
80th Percentile Industry Days to MDUFA V Decision	123	89	5		
Maximum Industry Days to MDUFA V Decision	359	332	54		
<b>Average Number of Total Days to MDUFA V Decision</b>	131.03	114.50	65.20		
20th Percentile Total Days to MDUFA V Decision	60	57	27		
40th Percentile Total Days to MDUFA V Decision	88	88	58		
60th Percentile Total Days to MDUFA V Decision	127	115	77		
80th Percentile Total Days to MDUFA V Decision	206	174	91		
Maximum Total Days to MDUFA V Decision	449	422	134		



**Table 6.6 OHT4 - Office of Surgical and Infection Control Devices**

**510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	676	601	243		
Number With MDUFA V Decision	586	469	75		
Number of SE Decision	570	466	75		
Number of NSE Decision	16	3	0		
Number of Withdrawal	52	38	2		
Number of Deleted	36	30	0		
Rate of SE Decision	97.27%	99.36%	100.00%		
Rate of NSE Decision	2.73%	0.64%	0.00%		
Rate of Withdrawal	7.69%	6.32%	0.82%		
Rate of Deleted	5.33%	4.99%	0.00%		

**Table 6.7 OHT4 - Office of Surgical and Infection Control Devices**

**510(k) Performance Metric - Submission Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	2	5	1		
Mean FDA Days for Submissions that Missed the Goal	96.50	92.20	91.00		
Mean Industry Days for Submissions that Missed the Goal	59.50	118.60	0.00		

**Table 6.8 OHT4 - Office of Surgical and Infection Control Devices**

**LDT 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		

**Table 6.9 OHT4 - Office of Surgical and Infection Control Devices**

**Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		



**Table 6.1 OHT5 - Office of Neurological and Physical Medicine Devices**  
**510(k) Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	314	306	170		
Closed Before First RTA or TS Action <sup>1</sup>	3	3	3		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	214	275	144		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	1	1	3		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	0	12		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	96	27	8		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	30.87%	8.91%	5.16%		

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

**Table 6.2 OHT5 - Office of Neurological and Physical Medicine Devices**  
**510(k) Substantive Interaction (SI) Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	298	300	152		
Deleted or Withdrawn Prior to SI	0	0	0		
SI Within 60 FDA Days	287	279	112		
SI Over 60 FDA Days	11	19	3		
SI Pending Within 60 FDA Days	0	2	37		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	0	0	0		
Current SI Performance Percent Within 60 FDA Days	96.31%	93.62%	97.39%		



**Table 6.3 OHT5 - Office of Neurological and Physical Medicine Devices**  
**510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interaction	298	298	115		
Average Number of FDA Days to Substantive Interaction	54.67	54.88	51.33		
20th Percentile FDA Days to Substantive Interaction	56	53	37		
40th Percentile FDA Days to Substantive Interaction	58	58	56		
60th Percentile FDA Days to Substantive Interaction	60	59	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	80	95	67		

**Table 6.4 OHT5 - Office of Neurological and Physical Medicine Devices**  
**510(k) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 95% Within 90 FDA Days</b>	<b>FY 2024 95% Within 90 FDA Days</b>	<b>FY 2025 95% Within 90 FDA Days</b>	<b>FY 2026 95% Within 90 FDA Days</b>	<b>FY 2027 95% Within 90 FDA Days</b>
510(k)s Accepted	298	300	152		
Non-MDUFA V Decision	33	24	0		
MDUFA V Decision (SE/NSE)	263	240	50		
MDUFA V Decision Within 90 FDA Days	259	232	50		
510(k)s Pending MDUFA V Decision	2	36	102		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	1	1	0		
Current Performance Percent Within 90 FDA Days	98.11%	96.27%	100.00%		



**Table 6.5 OHT5 - Office of Neurological and Physical Medicine Devices**  
**510(k) Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Average Review Cycles	1.75	1.75	1.36		
Number With MDUFA V Decision	263	240	50		
<b>Average Number of FDA Days to MDUFA V Decision</b>	77.86	77.33	58.36		
20th Percentile FDA Days to MDUFA V Decision	59	59	30		
40th Percentile FDA Days to MDUFA V Decision	87	86	49		
60th Percentile FDA Days to MDUFA V Decision	89	88	70		
80th Percentile FDA Days to MDUFA V Decision	90	90	87		
Maximum FDA Days to MDUFA V Decision	150	121	90		
<b>Average Number of Industry Days to MDUFA V Decision</b>	76.22	67.63	8.74		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	35	32	0		
60th Percentile Industry Days to MDUFA V Decision	90	78	0		
80th Percentile Industry Days to MDUFA V Decision	168	141	14		
Maximum Industry Days to MDUFA V Decision	367	200	80		
<b>Average Number of Total Days to MDUFA V Decision</b>	154.48	145.22	67.10		
20th Percentile Total Days to MDUFA V Decision	61	72	30		
40th Percentile Total Days to MDUFA V Decision	118	115	53		
60th Percentile Total Days to MDUFA V Decision	175	164	85		
80th Percentile Total Days to MDUFA V Decision	254	226	95		
Maximum Total Days to MDUFA V Decision	517	289	143		



**Table 6.6 OHT5 - Office of Neurological and Physical Medicine Devices**

**510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	298	300	152		
Number With MDUFA V Decision	263	240	50		
Number of SE Decision	245	222	50		
Number of NSE Decision	18	18	0		
Number of Withdrawal	9	8	0		
Number of Deleted	21	15	0		
Rate of SE Decision	93.16%	92.50%	100.00%		
Rate of NSE Decision	6.84%	7.50%	0.00%		
Rate of Withdrawal	3.02%	2.67%	0.00%		
Rate of Deleted	7.05%	5.00%	0.00%		

**Table 6.7 OHT5 - Office of Neurological and Physical Medicine Devices**

**510(k) Performance Metric - Submission Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	4	8	0		
Mean FDA Days for Submissions that Missed the Goal	123.25	100.25	N/A		
Mean Industry Days for Submissions that Missed the Goal	213.75	131.38	N/A		

**Table 6.8 OHT5 - Office of Neurological and Physical Medicine Devices**

**LDT 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		

**Table 6.9 OHT5 - Office of Neurological and Physical Medicine Devices**

**Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		



**Table 6.1 OHT6 - Office of Orthopedic Devices**  
**510(k) Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	619	563	282		
Closed Before First RTA or TS Action <sup>1</sup>	6	4	5		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	517	535	242		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	3	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	1	28		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	93	23	7		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	15.17%	4.12%	2.81%		

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

**Table 6.2 OHT6 - Office of Orthopedic Devices**  
**510(k) Substantive Interaction (SI) Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	605	553	246		
Deleted or Withdrawn Prior to SI	1	2	1		
SI Within 60 FDA Days	604	548	183		
SI Over 60 FDA Days	0	0	1		
SI Pending Within 60 FDA Days	0	3	61		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	0	0	0		
Current SI Performance Percent Within 60 FDA Days	100.00%	100.00%	99.46%		



**Table 6.3 OHT6 - Office of Orthopedic Devices****510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interaction	604	548	184		
Average Number of FDA Days to Substantive Interaction	49.84	50.01	47.22		
20th Percentile FDA Days to Substantive Interaction	30	30	29		
40th Percentile FDA Days to Substantive Interaction	56	56	55		
60th Percentile FDA Days to Substantive Interaction	58	58	58		
80th Percentile FDA Days to Substantive Interaction	60	60	59		
Maximum FDA Days to Substantive Interaction	60	60	61		

**Table 6.4 OHT6 - Office of Orthopedic Devices****510(k) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 95% Within 90 FDA Days</b>	<b>FY 2024 95% Within 90 FDA Days</b>	<b>FY 2025 95% Within 90 FDA Days</b>	<b>FY 2026 95% Within 90 FDA Days</b>	<b>FY 2027 95% Within 90 FDA Days</b>
510(k)s Accepted	605	553	246		
Non-MDUFA V Decision	51	42	2		
MDUFA V Decision (SE/NSE)	554	465	119		
MDUFA V Decision Within 90 FDA Days	554	465	119		
510(k)s Pending MDUFA V Decision	0	46	125		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	1		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	99.17%		



**Table 6.5 OHT6 - Office of Orthopedic Devices**  
**510(k) Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Average Review Cycles	1.48	1.42	1.13		
Number With MDUFA V Decision	554	465	119		
<b>Average Number of FDA Days to MDUFA V Decision</b>	65.77	64.16	50.11		
20th Percentile FDA Days to MDUFA V Decision	30	30	25		
40th Percentile FDA Days to MDUFA V Decision	59	59	30		
60th Percentile FDA Days to MDUFA V Decision	85	84	58		
80th Percentile FDA Days to MDUFA V Decision	89	88	83		
Maximum FDA Days to MDUFA V Decision	90	90	90		
<b>Average Number of Industry Days to MDUFA V Decision</b>	42.82	35.15	2.11		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	0	0		
60th Percentile Industry Days to MDUFA V Decision	18	4	0		
80th Percentile Industry Days to MDUFA V Decision	92	74	0		
Maximum Industry Days to MDUFA V Decision	354	247	35		
<b>Average Number of Total Days to MDUFA V Decision</b>	108.59	99.58	52.22		
20th Percentile Total Days to MDUFA V Decision	30	30	25		
40th Percentile Total Days to MDUFA V Decision	60	59	30		
60th Percentile Total Days to MDUFA V Decision	98	90	58		
80th Percentile Total Days to MDUFA V Decision	179	156	84		
Maximum Total Days to MDUFA V Decision	443	448	120		



**Table 6.6 OHT6 - Office of Orthopedic Devices**

**510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	605	553	246		
Number With MDUFA V Decision	554	465	119		
Number of SE Decision	544	461	119		
Number of NSE Decision	10	4	0		
Number of Withdrawal	37	29	1		
Number of Deleted	12	13	0		
Rate of SE Decision	98.19%	99.14%	100.00%		
Rate of NSE Decision	1.81%	0.86%	0.00%		
Rate of Withdrawal	6.12%	5.24%	0.41%		
Rate of Deleted	1.98%	2.35%	0.00%		

**Table 6.7 OHT6 - Office of Orthopedic Devices**

**510(k) Performance Metric - Submission Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		

**Table 6.8 OHT6 - Office of Orthopedic Devices**

**LDT 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		

**Table 6.9 OHT6 - Office of Orthopedic Devices**

**Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		



**Table 6.1 OHT7 - Office of In Vitro Diagnostics  
510(k) Acceptance Review Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	295	258	144		
Closed Before First RTA or TS Action <sup>1</sup>	7	13	2		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	243	227	120		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	5	4	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	1	15		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	40	13	7		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	13.89%	5.33%	5.51%		

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

**Table 6.2 OHT7 - Office of In Vitro Diagnostics  
510(k) Substantive Interaction (SI) Performance Goal**

<b>Substantive Interaction (SI) Goal</b>	<b>FY 2023 95% SI Within 60 FDA Days</b>	<b>FY 2024 95% SI Within 60 FDA Days</b>	<b>FY 2025 95% SI Within 60 FDA Days</b>	<b>FY 2026 95% SI Within 60 FDA Days</b>	<b>FY 2027 95% SI Within 60 FDA Days</b>
Eligible For SI	271	239	122		
Deleted or Withdrawn Prior to SI	3	0	0		
SI Within 60 FDA Days	266	236	93		
SI Over 60 FDA Days	0	1	2		
SI Pending Within 60 FDA Days	0	2	27		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	2	0	0		
Current SI Performance Percent Within 60 FDA Days	99.25%	99.58%	97.89%		



**Table 6.3 OHT7 - Office of In Vitro Diagnostics**

**510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interaction	266	237	95		
Average Number of FDA Days to Substantive Interaction	52.54	51.10	49.62		
20th Percentile FDA Days to Substantive Interaction	47	42	36		
40th Percentile FDA Days to Substantive Interaction	56	55	54		
60th Percentile FDA Days to Substantive Interaction	58	58	58		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	60	81	67		

**Table 6.4 OHT7 - Office of In Vitro Diagnostics**

**510(k) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 95% Within 90 FDA Days</b>	<b>FY 2024 95% Within 90 FDA Days</b>	<b>FY 2025 95% Within 90 FDA Days</b>	<b>FY 2026 95% Within 90 FDA Days</b>	<b>FY 2027 95% Within 90 FDA Days</b>
510(k)s Accepted	271	239	122		
Non-MDUFA V Decision	51	38	0		
MDUFA V Decision (SE/NSE)	220	167	45		
MDUFA V Decision Within 90 FDA Days	220	167	45		
510(k)s Pending MDUFA V Decision	0	34	77		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%		



**Table 6.5 OHT7 - Office of In Vitro Diagnostics**  
**510(k) Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Average Review Cycles	1.59	1.56	1.04		
Number With MDUFA V Decision	220	167	45		
<b>Average Number of FDA Days to MDUFA V Decision</b>	76.25	72.65	56.18		
20th Percentile FDA Days to MDUFA V Decision	59	39	28		
40th Percentile FDA Days to MDUFA V Decision	87	84	35		
60th Percentile FDA Days to MDUFA V Decision	89	88	74		
80th Percentile FDA Days to MDUFA V Decision	90	90	88		
Maximum FDA Days to MDUFA V Decision	90	90	90		
<b>Average Number of Industry Days to MDUFA V Decision</b>	80.81	65.32	0.47		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	0	0		
60th Percentile Industry Days to MDUFA V Decision	119	73	0		
80th Percentile Industry Days to MDUFA V Decision	177	161	0		
Maximum Industry Days to MDUFA V Decision	361	361	18		
<b>Average Number of Total Days to MDUFA V Decision</b>	157.05	137.97	56.64		
20th Percentile Total Days to MDUFA V Decision	60	52	28		
40th Percentile Total Days to MDUFA V Decision	90	90	35		
60th Percentile Total Days to MDUFA V Decision	205	158	74		
80th Percentile Total Days to MDUFA V Decision	265	245	90		
Maximum Total Days to MDUFA V Decision	451	451	105		



**Table 6.6 OHT7 - Office of In Vitro Diagnostics**

**510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	271	239	122		
Number With MDUFA V Decision	220	167	45		
Number of SE Decision	211	161	45		
Number of NSE Decision	9	6	0		
Number of Withdrawal	28	20	0		
Number of Deleted	23	18	0		
Rate of SE Decision	95.91%	96.41%	100.00%		
Rate of NSE Decision	4.09%	3.59%	0.00%		
Rate of Withdrawal	10.33%	8.37%	0.00%		
Rate of Deleted	8.49%	7.53%	0.00%		

**Table 6.7 OHT7 - Office of In Vitro Diagnostics**

**510(k) Performance Metric - Submission Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		

**Table 6.8 OHT7 - Office of In Vitro Diagnostics**

**LDT 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	2	4	0		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision (SE/NSE)	2	3	0		
MDUFA V Decision Within 90 FDA Days	2	3	0		
510(k)s Pending MDUFA V Decision	0	1	0		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	N/A		

**Table 6.9 OHT7 - Office of In Vitro Diagnostics**

**Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	269	235	122		
Non-MDUFA V Decision	51	38	0		
MDUFA V Decision (SE/NSE)	218	164	45		
MDUFA V Decision Within 90 FDA Days	218	164	45		
510(k)s Pending MDUFA V Decision	0	33	77		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%		



**Table 6.1 OHT8 - Office of Radiological Health  
510(k) Acceptance Review Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number Received	488	461	232		
Closed Before First RTA or TS Action <sup>1</sup>	4	2	1		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	441	447	198		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	2	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	0	28		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	41	12	5		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	8.47%	2.61%	2.46%		

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

**Table 6.2 OHT8 - Office of Radiological Health  
510(k) Substantive Interaction (SI) Performance Goal**

<b>Substantive Interaction (SI) Goal</b>	<b>FY 2023 95% SI Within 60 FDA Days</b>	<b>FY 2024 95% SI Within 60 FDA Days</b>	<b>FY 2025 95% SI Within 60 FDA Days</b>	<b>FY 2026 95% SI Within 60 FDA Days</b>	<b>FY 2027 95% SI Within 60 FDA Days</b>
Eligible For SI	476	455	201		
Deleted or Withdrawn Prior to SI	0	3	0		
SI Within 60 FDA Days	476	451	144		
SI Over 60 FDA Days	0	1	1		
SI Pending Within 60 FDA Days	0	0	56		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	0	0	0		
Current SI Performance Percent Within 60 FDA Days	100.00%	99.78%	99.31%		



**Table 6.3 OHT8 - Office of Radiological Health****510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number of Substantive Interaction	476	452	145		
Average Number of FDA Days to Substantive Interaction	49.51	50.89	51.72		
20th Percentile FDA Days to Substantive Interaction	35	46	48		
40th Percentile FDA Days to Substantive Interaction	53	55	55		
60th Percentile FDA Days to Substantive Interaction	57	58	58		
80th Percentile FDA Days to Substantive Interaction	59	59	60		
Maximum FDA Days to Substantive Interaction	60	61	61		

**Table 6.4 OHT8 - Office of Radiological Health****510(k) MDUFA V Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2023 95% Within 90 FDA Days</b>	<b>FY 2024 95% Within 90 FDA Days</b>	<b>FY 2025 95% Within 90 FDA Days</b>	<b>FY 2026 95% Within 90 FDA Days</b>	<b>FY 2027 95% Within 90 FDA Days</b>
510(k)s Accepted	476	455	201		
Non-MDUFA V Decision	31	29	0		
MDUFA V Decision (SE/NSE)	445	387	52		
MDUFA V Decision Within 90 FDA Days	445	387	52		
510(k)s Pending MDUFA V Decision	0	39	149		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%		



**Table 6.5 OHT8 - Office of Radiological Health  
510(k) Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Average Review Cycles	1.72	1.74	1.35		
Number With MDUFA V Decision	445	387	52		
<b>Average Number of FDA Days to MDUFA V Decision</b>	71.52	73.62	60.75		
20th Percentile FDA Days to MDUFA V Decision	52	55	33		
40th Percentile FDA Days to MDUFA V Decision	79	83	55		
60th Percentile FDA Days to MDUFA V Decision	86	87	75		
80th Percentile FDA Days to MDUFA V Decision	89	89	87		
Maximum FDA Days to MDUFA V Decision	90	90	90		
<b>Average Number of Industry Days to MDUFA V Decision</b>	63.50	59.26	12.38		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	24	27	0		
60th Percentile Industry Days to MDUFA V Decision	62	58	0		
80th Percentile Industry Days to MDUFA V Decision	138	112	20		
Maximum Industry Days to MDUFA V Decision	182	182	86		
<b>Average Number of Total Days to MDUFA V Decision</b>	135.03	132.89	73.13		
20th Percentile Total Days to MDUFA V Decision	56	60	37		
40th Percentile Total Days to MDUFA V Decision	107	110	60		
60th Percentile Total Days to MDUFA V Decision	146	145	82		
80th Percentile Total Days to MDUFA V Decision	222	199	103		
Maximum Total Days to MDUFA V Decision	272	270	153		



**Table 6.6 OHT8 - Office of Radiological Health**

**510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	476	455	201		
Number With MDUFA V Decision	445	387	52		
Number of SE Decision	438	377	52		
Number of NSE Decision	7	10	0		
Number of Withdrawal	16	22	0		
Number of Deleted	14	7	0		
Rate of SE Decision	98.43%	97.42%	100.00%		
Rate of NSE Decision	1.57%	2.58%	0.00%		
Rate of Withdrawal	3.36%	4.84%	0.00%		
Rate of Deleted	2.94%	1.54%	0.00%		

**Table 6.7 OHT8 - Office of Radiological Health**

**510(k) Performance Metric - Submission Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		

**Table 6.8 OHT8 - Office of Radiological Health**

**LDT 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		

**Table 6.9 OHT8 - Office of Radiological Health**

**Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k)s Accepted	N/A	N/A	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		



## **Section 7    510(k) Annual General Metrics**

510(k) Annual Metrics and Goals will be reported in the Annual Report.

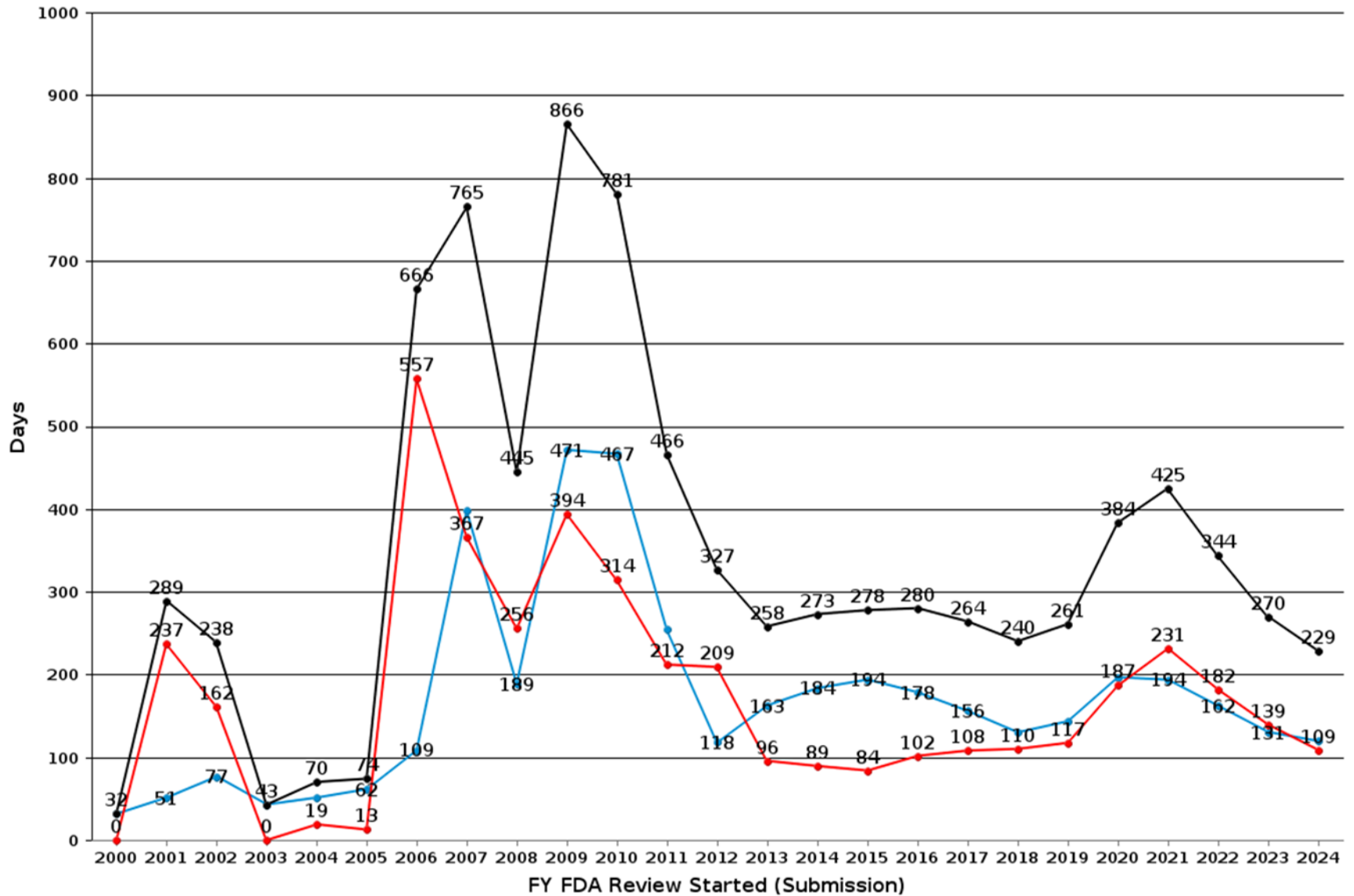


# De Novos

## Q2FY2025



De Novo Average Days to MDUFA Decision as of: 3/31/25



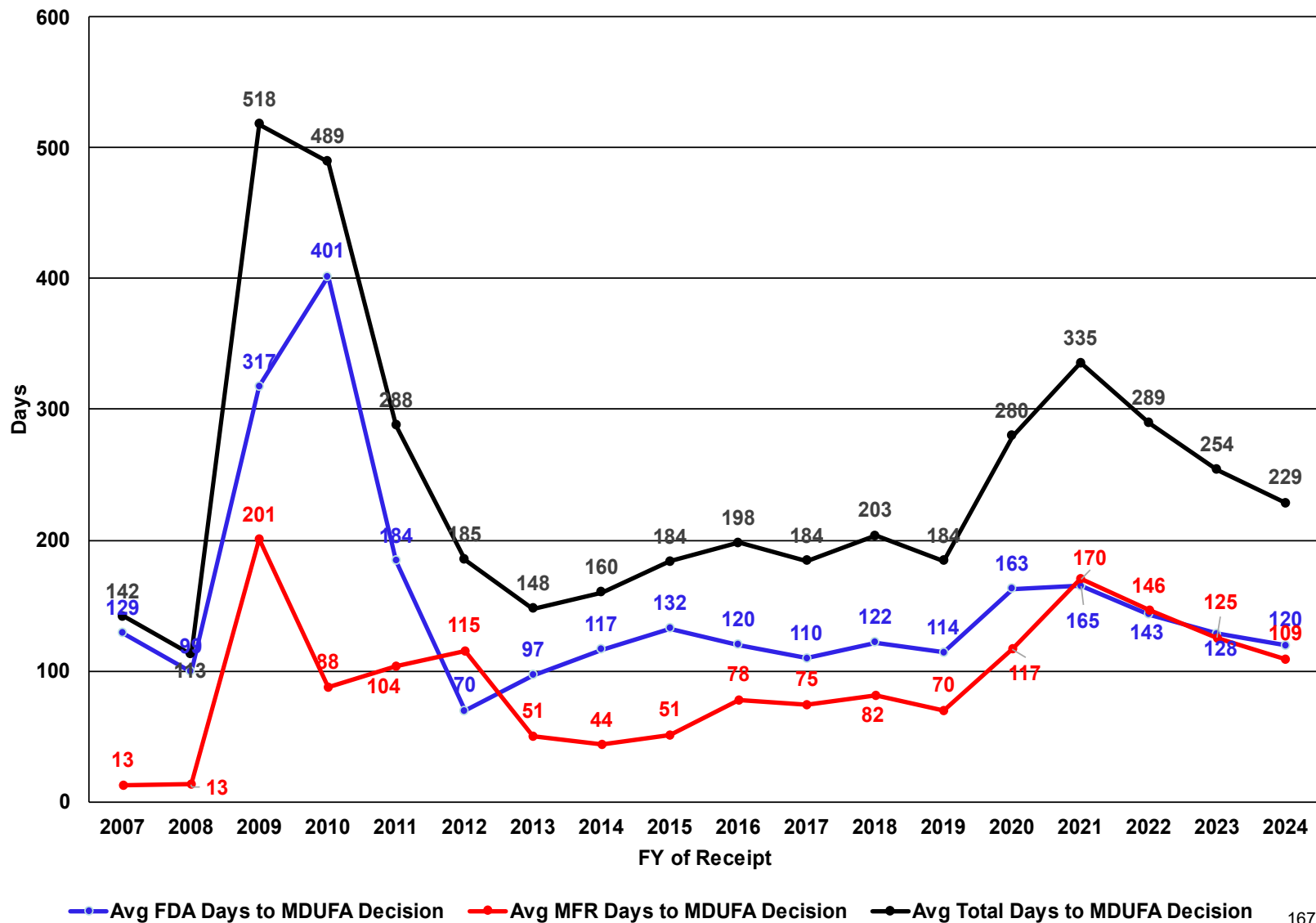
Cohorts not yet closed: 2024: 66.7%

● Avg FDA Days to MDUFA ● Avg MFR Days to MDUFA ● Avg Total Days to MDUFA



# Average Time to MDUFA Decision: De Novos

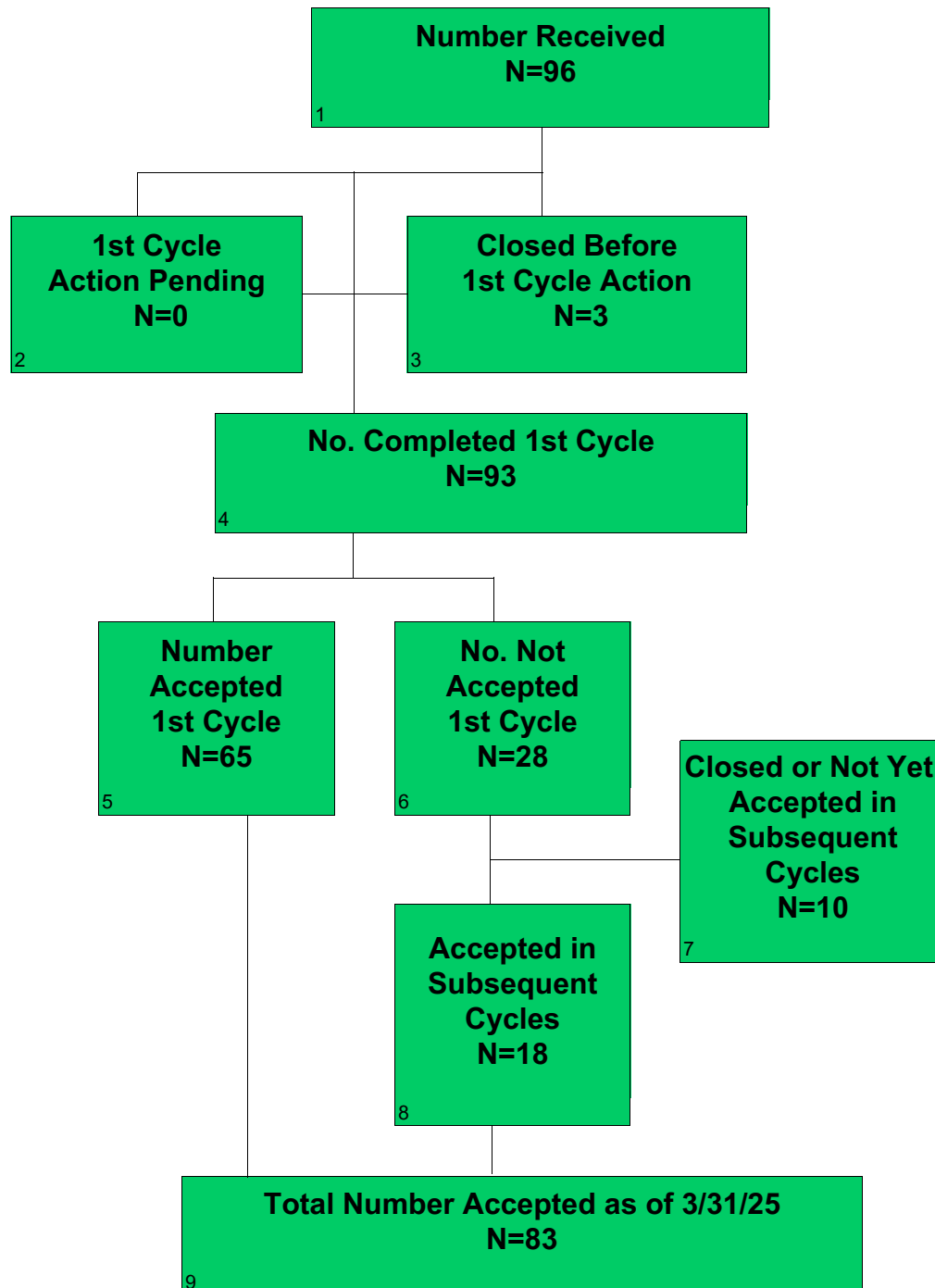
(66.7% closure comparison)





# CDRH De Novo - FY 2023 as of 3/31/25

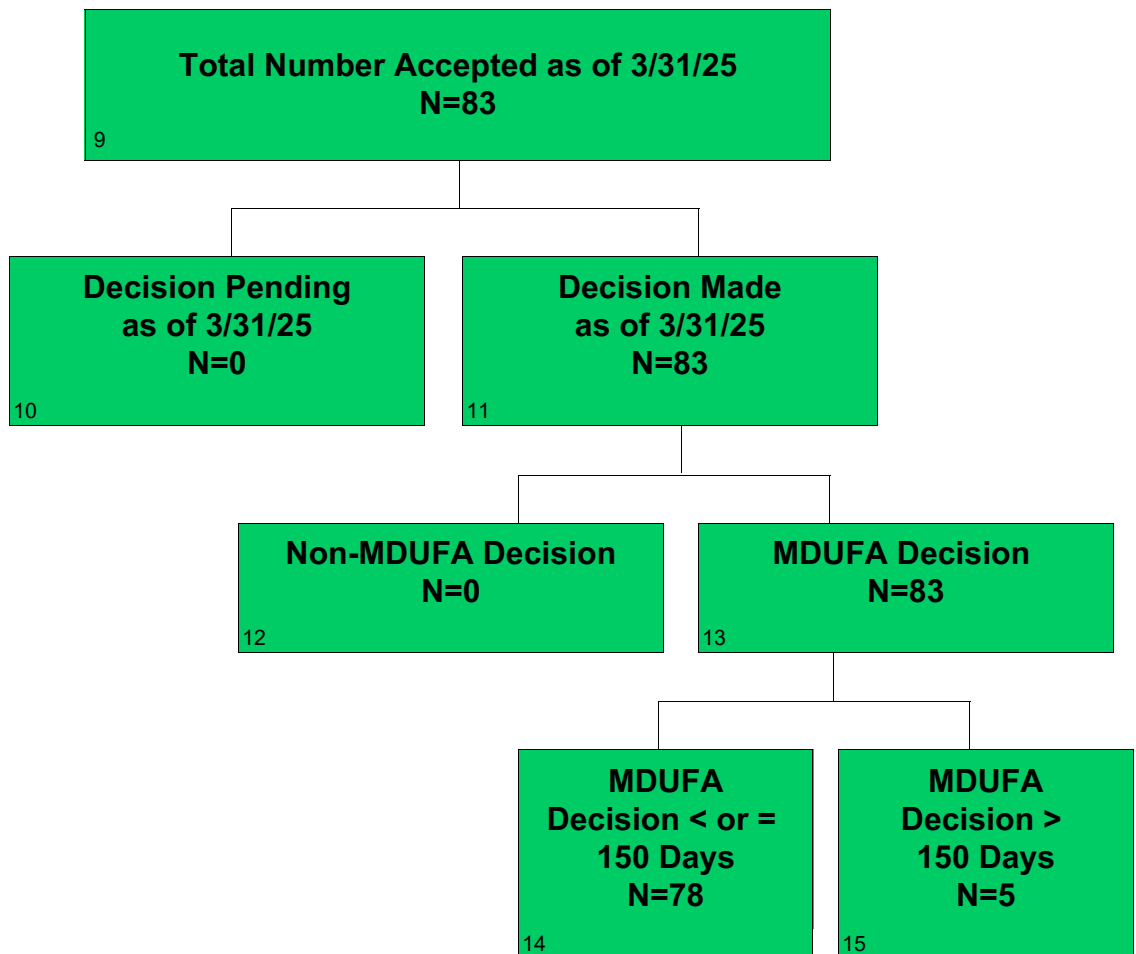
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# CDRH De Novo - FY 2023 as of 3/31/25 Continued

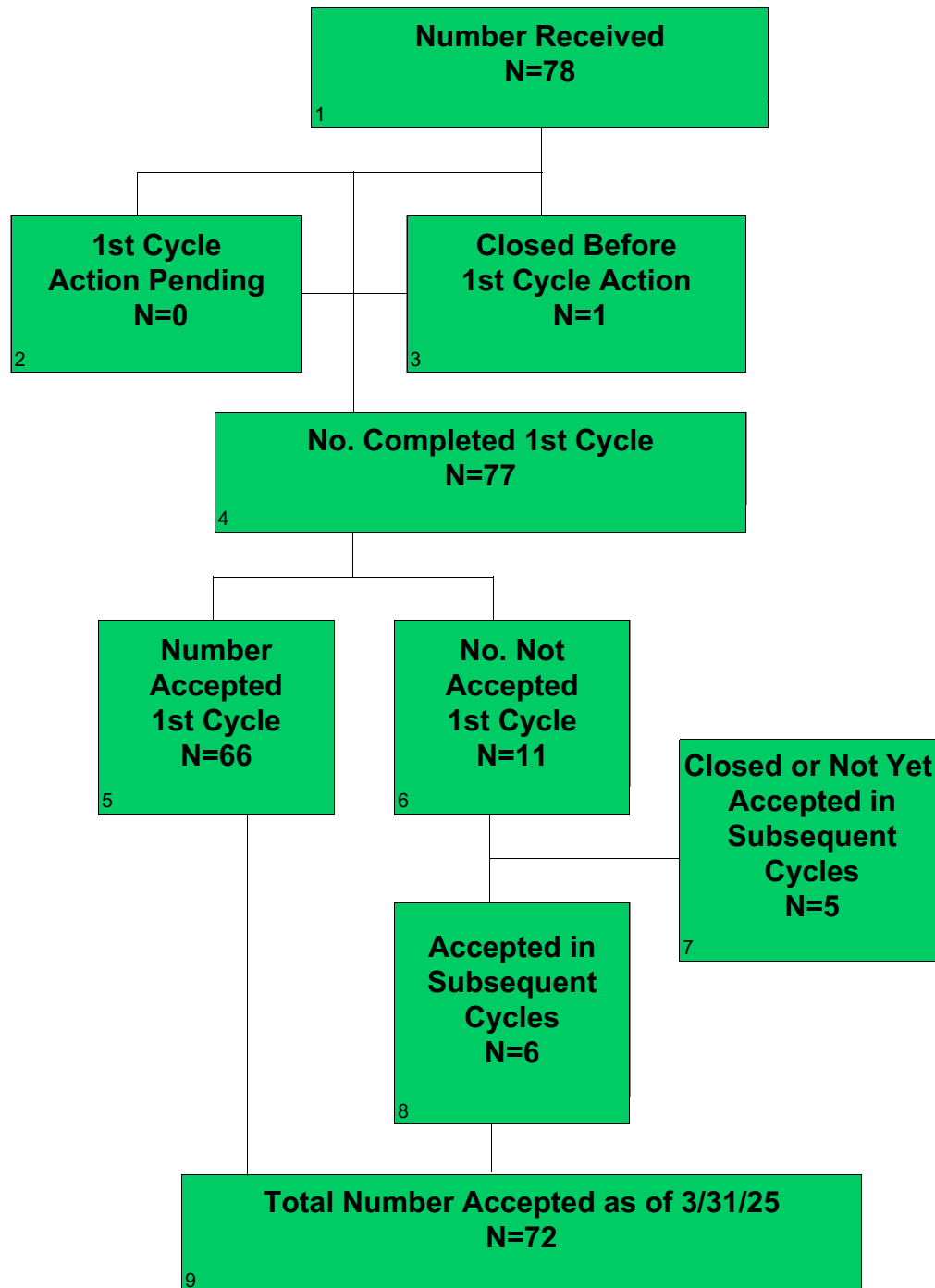
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# CDRH De Novo - FY 2024 as of 3/31/25

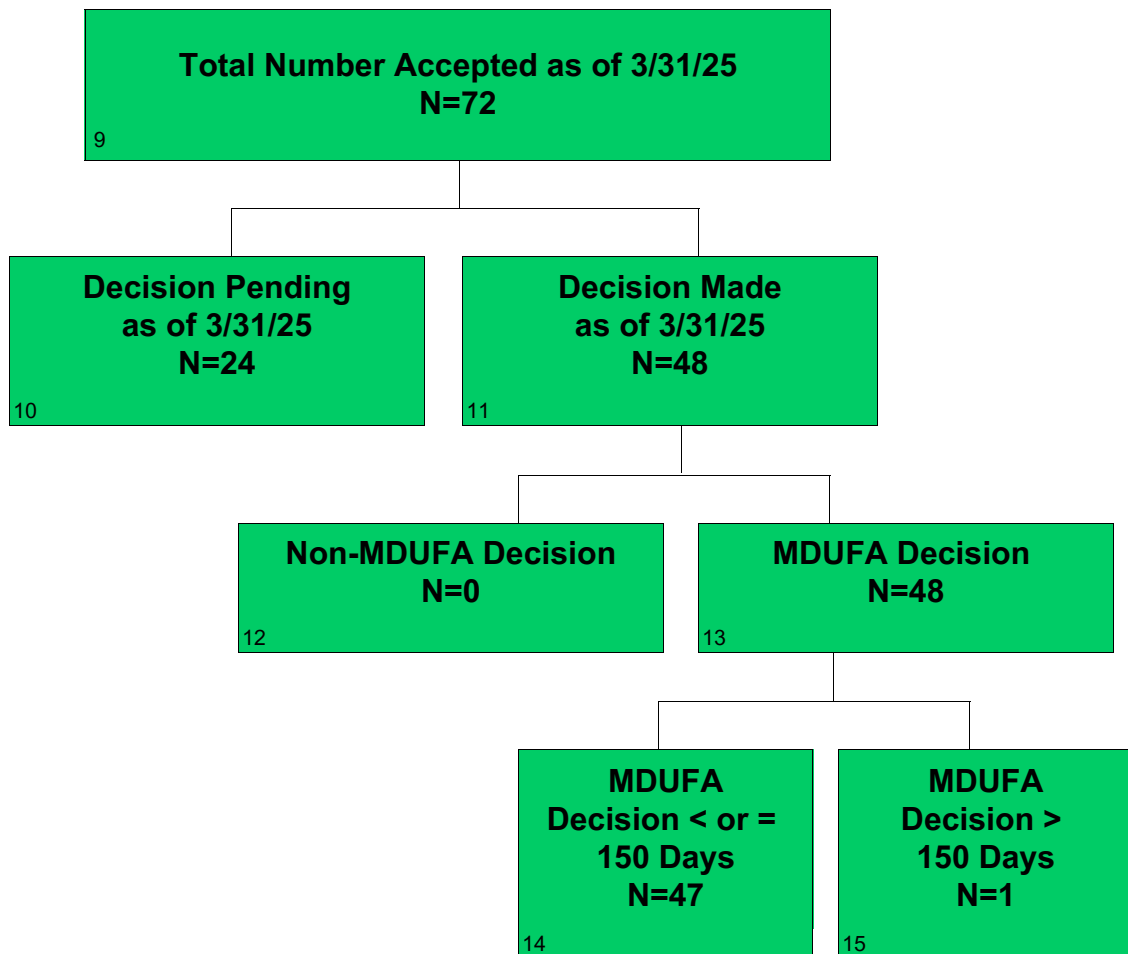
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# CDRH De Novo - FY 2024 as of 3/31/25 Continued

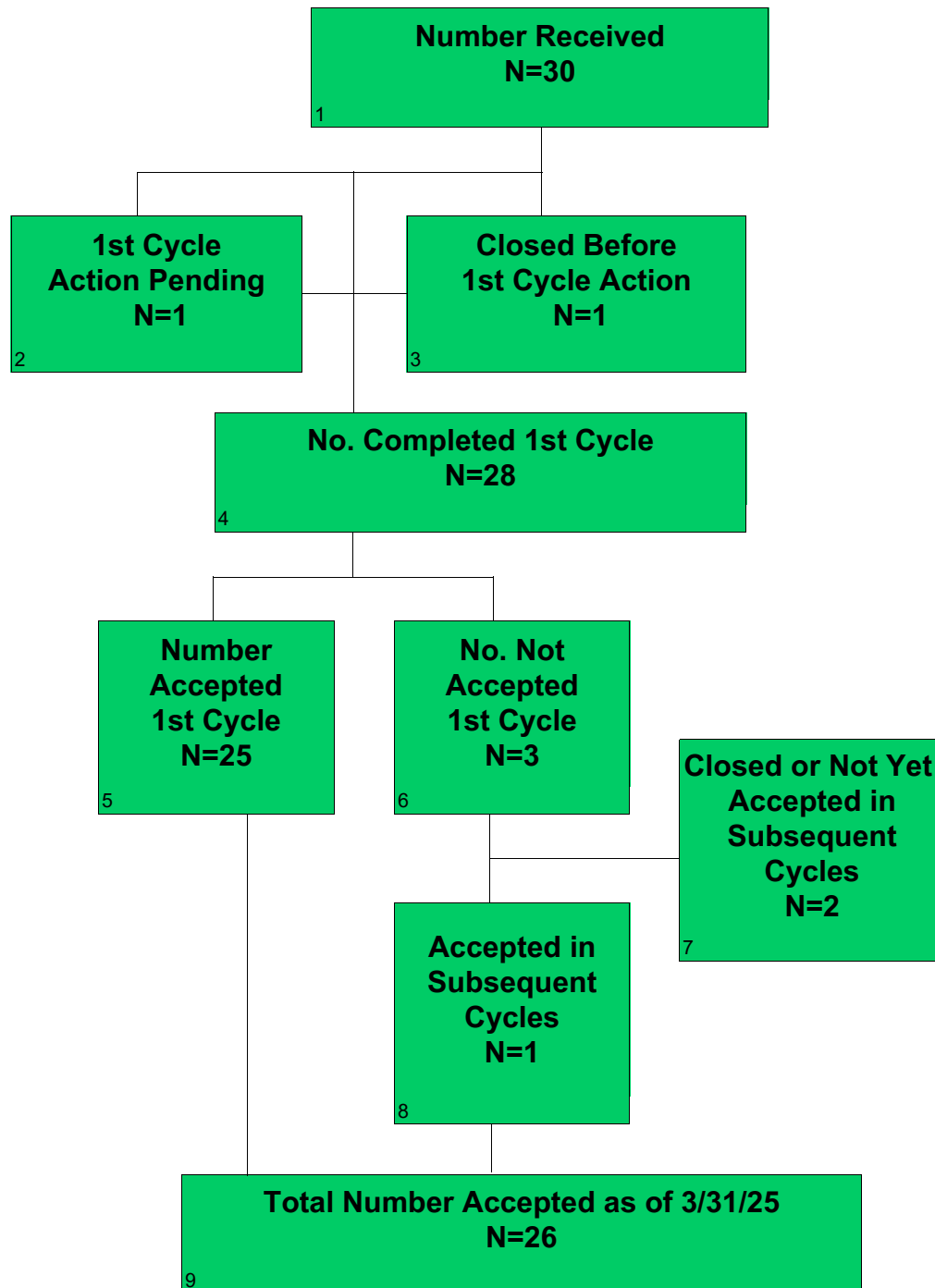
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# CDRH De Novo - FY 2025 as of 3/31/25

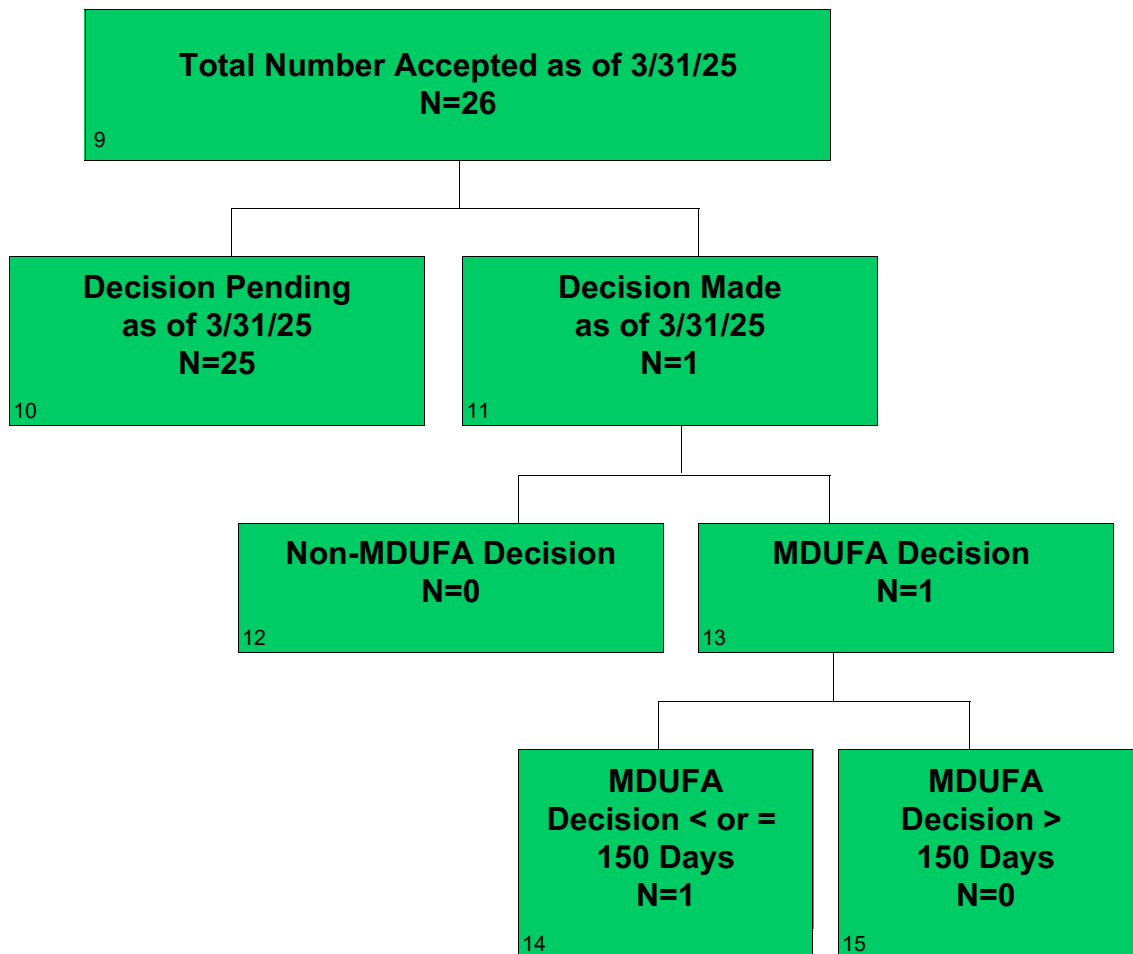
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# CDRH De Novo - FY 2025 as of 3/31/25 Continued

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Section 8 De Novo Center Level Metrics

Table 8.1 CDRH - De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	96	78	30		
Closed Before First RTA or TS Action	3	1	1		
Number Accepted or Passed TS on First Cycle	65	66	25		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	1		
Number Not Accepted or Failed TS on First Cycle	28	11	3		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	30.11%	14.29%	10.71%		

1.The data contained in this row should be combined with the data in the row above, “Number Accepted or Passed TS on First Cycle”, to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 5 in flowchart).

Table 8.2 CDRH - De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	83	72	26		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	83	48	1		
MDUFA Decision Within 150 FDA Days	78	47	1		
De Novos Pending MDUFA Decision	0	24	25		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	93.98%	97.92%	100.00%		

Table 8.3 CDRH - De Novo Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.69	1.54	1.00		
Number With MDUFA Decision	83	48	1		
Average FDA Days to MDUFA Decision	130.60	119.60	150.00		
20th Percentile FDA Days to MDUFA Decision	75	75	150		
40th Percentile FDA Days to MDUFA Decision	148	119	150		
60th Percentile FDA Days to MDUFA Decision	150	148	150		
80th Percentile FDA Days to MDUFA Decision	150	150	150		
Maximum FDA Days to MDUFA Decision	251	151	150		
Average Industry Days to MDUFA Decision	139.47	108.90	N/A		
20th Percentile Industry Days to MDUFA Decision	72	0	0		
40th Percentile Industry Days to MDUFA Decision	152	114	0		



60th Percentile Industry Days to MDUFA Decision	178	172	0		
80th Percentile Industry Days to MDUFA Decision	181	180	0		
Maximum Industry Days to MDUFA Decision	350	185	0		
<b>Average Total Days to MDUFA Decision</b>	270.07	228.50	150.00		
20th Percentile Total Days to MDUFA Decision	214	114	150		
40th Percentile Total Days to MDUFA Decision	256	231	150		
60th Percentile Total Days to MDUFA Decision	303	269	150		
80th Percentile Total Days to MDUFA Decision	329	325	150		
Maximum Total Days to MDUFA Decision	437	330	150		

**Table 8.4 CDRH - De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	83	72	26		
Number With MDUFA Decision	83	48	1		
Number With Granted Decision	37	21	0		
Number With Declined Decision	18	11	1		
Number of Withdrawal	17	10	0		
Number of Deleted	11	6	0		
Rate of Granted Decision	44.58%	43.75%	0.00%		
Rate of Declined Decision	21.69%	22.92%	100.00%		
Rate of Withdrawal	20.48%	20.83%	0.00%		
Rate of Deleted	13.25%	12.50%	0.00%		

**Table 8.5 CDRH - De Novo Performance Metrics-Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	5	1	0		
Mean FDA Days for Submissions that Missed the Goal	194.80	151.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	111.20	150.00	N/A		

**Table 8.6 CDRH - LDT De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	1	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	1	0	0		
MDUFA Decision Within 150 FDA Days	1	0	0		
De Novos Pending MDUFA Decision	0	0	0		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	N/A	N/A		



Table 8.7 CDRH - Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	19	18	4		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	19	12	0		
MDUFA Decision Within 150 FDA Days	19	12	0		
De Novos Pending MDUFA Decision	0	6	4		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	N/A		

Table 8.8 CDRH - De Novo Annual General Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Accepted First RTA Cycle	83	72	26		
Average Number of Days to Accept / Refuse to Accept on First RTA Cycle	12.23	11.44	11.73		



## Section 8 - De Novo Office Level Metrics

**Table 8.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices  
De Novo Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	12	13	3		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	6	10	1		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted or Failed TS on First Cycle	6	3	2		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	50.00%	23.08%	66.67%		

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 8.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices  
De Novo MDUFA V Decision Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	11	12	2		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	11	7	0		
MDUFA Decision Within 150 FDA Days	8	6	0		
De Novos Pending MDUFA Decision	0	5	2		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	72.73%	85.71%	N/A		

**Table 8.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices  
De Novo Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.55	1.57	N/A		
Number With MDUFA Decision	11	7	0		
Average FDA Days to MDUFA Decision	130.82	118.43	N/A		
20th Percentile FDA Days to MDUFA Decision	73	77	0		
40th Percentile FDA Days to MDUFA Decision	75	109	0		



60th Percentile FDA Days to MDUFA Decision	150	148	0		
80th Percentile FDA Days to MDUFA Decision	178	150	0		
Maximum FDA Days to MDUFA Decision	251	151	0		
<b>Average Industry Days to MDUFA Decision</b>	137.45	105.29	N/A		
20th Percentile Industry Days to MDUFA Decision	81	27	0		
40th Percentile Industry Days to MDUFA Decision	152	135	0		
60th Percentile Industry Days to MDUFA Decision	178	138	0		
80th Percentile Industry Days to MDUFA Decision	182	148	0		
Maximum Industry Days to MDUFA Decision	189	177	0		
<b>Average Total Days to MDUFA Decision</b>	268.27	223.71	N/A		
20th Percentile Total Days to MDUFA Decision	231	110	0		
40th Percentile Total Days to MDUFA Decision	255	242	0		
60th Percentile Total Days to MDUFA Decision	262	284	0		
80th Percentile Total Days to MDUFA Decision	328	298	0		
Maximum Total Days to MDUFA Decision	343	326	0		

**Table 8.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices  
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete  
Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	11	12	2		
Number With MDUFA Decision	11	7	0		
Number With Granted Decision	5	3	0		
Number With Declined Decision	1	1	0		
Number of Withdrawal	1	3	0		
Number of Deleted	4	0	0		
Rate of Granted Decision	45.45%	42.86%	N/A		
Rate of Declined Decision	9.09%	14.29%	N/A		
Rate of Withdrawal	9.09%	42.86%	N/A		
Rate of Deleted	36.36%	0.00%	N/A		



**Table 8.5 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices  
De Novo Performance Metrics-Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	3	1	0		
Mean FDA Days for Submissions That Missed the Goal	206.67	151.00	N/A		
Mean Industry Days for Submissions That Missed the Goal	122.33	150.00	N/A		

**Table 8.6 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices  
LDT De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA V Decision	0	0	0		
De Novos Pending MDUFA V Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		

**Table 8.7 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices  
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA V Decision	0	0	0		
De Novos Pending MDUFA V Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		



## Section 8 - De Novo Office Level Metrics

**Table 8.1 OHT2 - Office of Cardiovascular Devices  
De Novo Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	12	4	1		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	10	4	1		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted or Failed TS on First Cycle	2	0	0		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	16.67%	0.00%	0.00%		

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 8.2 OHT2 - Office of Cardiovascular Devices  
De Novo MDUFA V Decision Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	10	4	1		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	10	3	0		
MDUFA Decision Within 150 FDA Days	10	3	0		
De Novos Pending MDUFA Decision	0	1	1		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	N/A		

**Table 8.3 OHT2 - Office of Cardiovascular Devices  
De Novo Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.80	1.67	N/A		
Number With MDUFA Decision	10	3	0		
Average FDA Days to MDUFA Decision	137.10	149.67	N/A		
20th Percentile FDA Days to MDUFA Decision	140	149	0		
40th Percentile FDA Days to MDUFA Decision	150	150	0		
60th Percentile FDA Days to MDUFA Decision	150	150	0		



80th Percentile FDA Days to MDUFA Decision	150	150	0		
Maximum FDA Days to MDUFA Decision	150	150	0		
<b>Average Industry Days to MDUFA Decision</b>	114.40	119.00	N/A		
20th Percentile Industry Days to MDUFA Decision	47	71	0		
40th Percentile Industry Days to MDUFA Decision	90	142	0		
60th Percentile Industry Days to MDUFA Decision	178	178	0		
80th Percentile Industry Days to MDUFA Decision	180	179	0		
Maximum Industry Days to MDUFA Decision	183	180	0		
<b>Average Total Days to MDUFA Decision</b>	251.50	268.67	N/A		
20th Percentile Total Days to MDUFA Decision	197	220	0		
40th Percentile Total Days to MDUFA Decision	238	291	0		
60th Percentile Total Days to MDUFA Decision	267	328	0		
80th Percentile Total Days to MDUFA Decision	328	329	0		
Maximum Total Days to MDUFA Decision	329	330	0		

**Table 8.4 OHT2 - Office of Cardiovascular Devices**  
**De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	10	4	1		
Number With MDUFA Decision	10	3	0		
Number With Granted Decision	6	2	0		
Number With Declined Decision	3	1	0		
Number of Withdrawal	0	0	0		
Number of Deleted	1	0	0		
Rate of Granted Decision	60.00%	66.67%	N/A		
Rate of Declined Decision	30.00%	33.33%	N/A		
Rate of Withdrawal	0.00%	0.00%	N/A		
Rate of Deleted	10.00%	0.00%	N/A		



**Table 8.5 OHT2 - Office of Cardiovascular Devices**  
**De Novo Performance Metrics-Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A	N/A		

**Table 8.6 OHT2 - Office of Cardiovascular Devices**  
**LDT De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA V Decision	0	0	0		
De Novos Pending MDUFA V Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		

**Table 8.7 OHT2 - Office of Cardiovascular Devices**  
**Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA V Decision	0	0	0		
De Novos Pending MDUFA V Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		



## Section 8 - De Novo Office Level Metrics

**Table 8.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
De Novo Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	11	8	3		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	9	7	2		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	1		
Number Not Accepted or Failed TS on First Cycle	2	1	0		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	18.18%	12.50%	0.00%		

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 8.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
De Novo MDUFA V Decision Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	11	8	2		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	11	3	0		
MDUFA Decision Within 150 FDA Days	11	3	0		
De Novos Pending MDUFA Decision	0	5	2		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	N/A		

**Table 8.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
De Novo Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.55	2.00	N/A		
Number With MDUFA Decision	11	3	0		
Average FDA Days to MDUFA Decision	128.45	147.33	N/A		
20th Percentile FDA Days to MDUFA Decision	74	146	0		



40th Percentile FDA Days to MDUFA Decision	148	148	0		
60th Percentile FDA Days to MDUFA Decision	150	149	0		
80th Percentile FDA Days to MDUFA Decision	150	149	0		
Maximum FDA Days to MDUFA Decision	150	149	0		
<b>Average Industry Days to MDUFA Decision</b>	122.73	180.00	N/A		
20th Percentile Industry Days to MDUFA Decision	83	179	0		
40th Percentile Industry Days to MDUFA Decision	124	180	0		
60th Percentile Industry Days to MDUFA Decision	163	180	0		
80th Percentile Industry Days to MDUFA Decision	180	181	0		
Maximum Industry Days to MDUFA Decision	214	181	0		
<b>Average Total Days to MDUFA Decision</b>	251.18	327.33	N/A		
20th Percentile Total Days to MDUFA Decision	231	326	0		
40th Percentile Total Days to MDUFA Decision	247	327	0		
60th Percentile Total Days to MDUFA Decision	274	328	0		
80th Percentile Total Days to MDUFA Decision	293	329	0		
Maximum Total Days to MDUFA Decision	330	329	0		

**Table 8.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete  
Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	11	8	2		
Number With MDUFA Decision	11	3	0		
Number With Granted Decision	7	1	0		
Number With Declined Decision	1	1	0		
Number of Withdrawal	1	1	0		
Number of Deleted	2	0	0		
Rate of Granted Decision	63.64%	33.33%	N/A		
Rate of Declined Decision	9.09%	33.33%	N/A		
Rate of Withdrawal	9.09%	33.33%	N/A		
Rate of Deleted	18.18%	0.00%	N/A		



**Table 8.5 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
De Novo Performance Metrics-Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A	N/A		

**Table 8.6 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
LDT De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA V Decision	0	0	0		
De Novos Pending MDUFA V Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		

**Table 8.7 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA V Decision	0	0	0		
De Novos Pending MDUFA V Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		



## Section 8 - De Novo Office Level Metrics

**Table 8.1 OHT4 - Office of Surgical and Infection Control Devices  
De Novo Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	14	4		
Closed Before First RTA or TS Action	1	0	0		
Number Accepted or Passed TS on First Cycle	11	11	4		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted or Failed TS on First Cycle	9	3	0		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	45.00%	21.43%	0.00%		

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 8.2 OHT4 - Office of Surgical and Infection Control Devices  
De Novo MDUFA V Decision Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	15	12	4		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	15	11	0		
MDUFA Decision Within 150 FDA Days	13	11	0		
De Novos Pending MDUFA Decision	0	1	4		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	86.67%	100.00%	N/A		

**Table 8.3 OHT4 - Office of Surgical and Infection Control Devices  
De Novo Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.80	1.45	N/A		
Number With MDUFA Decision	15	11	0		
Average FDA Days to MDUFA Decision	126.87	117.18	N/A		
20th Percentile FDA Days to MDUFA Decision	75	74	0		
40th Percentile FDA Days to MDUFA Decision	143	96	0		
60th Percentile FDA Days to MDUFA Decision	148	149	0		



80th Percentile FDA Days to MDUFA Decision	150	150	0		
Maximum FDA Days to MDUFA Decision	203	150	0		
<b>Average Industry Days to MDUFA Decision</b>	134.87	124.64	N/A		
20th Percentile Industry Days to MDUFA Decision	80	0	0		
40th Percentile Industry Days to MDUFA Decision	156	165	0		
60th Percentile Industry Days to MDUFA Decision	180	172	0		
80th Percentile Industry Days to MDUFA Decision	181	180	0		
Maximum Industry Days to MDUFA Decision	198	185	0		
<b>Average Total Days to MDUFA Decision</b>	261.73	241.82	N/A		
20th Percentile Total Days to MDUFA Decision	228	150	0		
40th Percentile Total Days to MDUFA Decision	254	240	0		
60th Percentile Total Days to MDUFA Decision	302	315	0		
80th Percentile Total Days to MDUFA Decision	329	324	0		
Maximum Total Days to MDUFA Decision	346	330	0		

**Table 8.4 OHT4 - Office of Surgical and Infection Control Devices**  
**De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	15	12	4		
Number With MDUFA Decision	15	11	0		
Number With Granted Decision	7	7	0		
Number With Declined Decision	2	1	0		
Number of Withdrawal	5	2	0		
Number of Deleted	1	1	0		
Rate of Granted Decision	46.67%	63.64%	N/A		
Rate of Declined Decision	13.33%	9.09%	N/A		
Rate of Withdrawal	33.33%	18.18%	N/A		
Rate of Deleted	6.67%	9.09%	N/A		



**Table 8.5 OHT4 - Office of Surgical and Infection Control Devices**  
**De Novo Performance Metrics-Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	2	0	0		
Mean FDA Days for Submissions That Missed the Goal	177.00	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	94.50	N/A	N/A		

**Table 8.6 OHT4 - Office of Surgical and Infection Control Devices**  
**LDT De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA V Decision	0	0	0		
De Novos Pending MDUFA V Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		

**Table 8.7 OHT4 - Office of Surgical and Infection Control Devices**  
**Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA V Decision	0	0	0		
De Novos Pending MDUFA V Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		



## Section 8 - De Novo Office Level Metrics

**Table 8.1 OHT5 - Office of Neurological and Physical Medicine Devices  
De Novo Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	10	12	9		
Closed Before First RTA or TS Action	1	0	0		
Number Accepted or Passed TS on First Cycle	5	11	9		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted or Failed TS on First Cycle	4	1	0		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	44.44%	8.33%	0.00%		

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 8.2 OHT5 - Office of Neurological and Physical Medicine Devices  
De Novo MDUFA V Decision Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	9	12	9		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	9	10	1		
MDUFA Decision Within 150 FDA Days	9	10	1		
De Novos Pending MDUFA Decision	0	2	8		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%		

**Table 8.3 OHT5 - Office of Neurological and Physical Medicine Devices  
De Novo Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	2.11	1.60	1.00		
Number With MDUFA Decision	9	10	1		
Average FDA Days to MDUFA Decision	141.44	112.70	150.00		
20th Percentile FDA Days to MDUFA Decision	149	75	150		
40th Percentile FDA Days to MDUFA Decision	150	83	150		
60th Percentile FDA Days to MDUFA Decision	150	145	150		



80th Percentile FDA Days to MDUFA Decision	150	148	150		
Maximum FDA Days to MDUFA Decision	150	150	150		
<b>Average Industry Days to MDUFA Decision</b>	145.56	97.20	N/A		
20th Percentile Industry Days to MDUFA Decision	112	0	0		
40th Percentile Industry Days to MDUFA Decision	154	77	0		
60th Percentile Industry Days to MDUFA Decision	172	139	0		
80th Percentile Industry Days to MDUFA Decision	182	179	0		
Maximum Industry Days to MDUFA Decision	231	183	0		
<b>Average Total Days to MDUFA Decision</b>	287.00	209.90	150.00		
20th Percentile Total Days to MDUFA Decision	237	85	150		
40th Percentile Total Days to MDUFA Decision	300	223	150		
60th Percentile Total Days to MDUFA Decision	313	257	150		
80th Percentile Total Days to MDUFA Decision	326	277	150		
Maximum Total Days to MDUFA Decision	381	327	150		

**Table 8.4 OHT5 - Office of Neurological and Physical Medicine Devices**  
**De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	9	12	9		
Number With MDUFA Decision	9	10	1		
Number With Granted Decision	3	2	0		
Number With Declined Decision	5	5	1		
Number of Withdrawal	0	1	0		
Number of Deleted	1	2	0		
Rate of Granted Decision	33.33%	20.00%	0.00%		
Rate of Declined Decision	55.56%	50.00%	100.00%		
Rate of Withdrawal	0.00%	10.00%	0.00%		
Rate of Deleted	11.11%	20.00%	0.00%		



**Table 8.5 OHT5 - Office of Neurological and Physical Medicine Devices**  
**De Novo Performance Metrics-Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A	N/A		

**Table 8.6 OHT5 - Office of Neurological and Physical Medicine Devices**  
**LDT De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA V Decision	0	0	0		
De Novos Pending MDUFA V Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		

**Table 8.7 OHT5 - Office of Neurological and Physical Medicine Devices**  
**Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA V Decision	0	0	0		
De Novos Pending MDUFA V Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		



## Section 8 - De Novo Office Level Metrics

**Table 8.1 OHT6 - Office of Orthopedic Devices  
De Novo Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	2	2		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	3	2	2		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted or Failed TS on First Cycle	0	0	0		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	0.00%	0.00%	0.00%		

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 8.2 OHT6 - Office of Orthopedic Devices  
De Novo MDUFA V Decision Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	3	2	2		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	3	0	0		
MDUFA Decision Within 150 FDA Days	3	0	0		
De Novos Pending MDUFA Decision	0	2	2		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	N/A	N/A		

**Table 8.3 OHT6 - Office of Orthopedic Devices  
De Novo Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.67	N/A	N/A		
Number With MDUFA Decision	3	0	0		
Average FDA Days to MDUFA Decision	149.00	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	148	0	0		
40th Percentile FDA Days to MDUFA Decision	149	0	0		
60th Percentile FDA Days to MDUFA Decision	149	0	0		



80th Percentile FDA Days to MDUFA Decision	150	0	0		
Maximum FDA Days to MDUFA Decision	150	0	0		
<b>Average Industry Days to MDUFA Decision</b>	119.33	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	71	0	0		
40th Percentile Industry Days to MDUFA Decision	142	0	0		
60th Percentile Industry Days to MDUFA Decision	178	0	0		
80th Percentile Industry Days to MDUFA Decision	179	0	0		
Maximum Industry Days to MDUFA Decision	180	0	0		
<b>Average Total Days to MDUFA Decision</b>	268.33	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	220	0	0		
40th Percentile Total Days to MDUFA Decision	292	0	0		
60th Percentile Total Days to MDUFA Decision	328	0	0		
80th Percentile Total Days to MDUFA Decision	329	0	0		
Maximum Total Days to MDUFA Decision	329	0	0		

**Table 8.4 OHT6 - Office of Orthopedic Devices**  
**De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
De Novos Accepted	3	2	2		
Number With MDUFA Decision	3	0	0		
Number With Granted Decision	2	0	0		
Number With Declined Decision	1	0	0		
Number of Withdrawal	0	0	0		
Number of Deleted	0	0	0		
Rate of Granted Decision	66.67%	N/A	N/A		
Rate of Declined Decision	33.33%	N/A	N/A		
Rate of Withdrawal	0.00%	N/A	N/A		
Rate of Deleted	0.00%	N/A	N/A		



**Table 8.5 OHT6 - Office of Orthopedic Devices**  
**De Novo Performance Metrics-Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A	N/A		

**Table 8.6 OHT6 - Office of Orthopedic Devices**  
**LDT De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA V Decision	0	0	0		
De Novos Pending MDUFA V Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		

**Table 8.7 OHT6 - Office of Orthopedic Devices**  
**Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA V Decision	0	0	0		
De Novos Pending MDUFA V Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		



## Section 8 - De Novo Office Level Metrics

**Table 8.1 OHT7 - Office of In Vitro Diagnostics  
De Novo Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	23	20	6		
Closed Before First RTA or TS Action	1	1	1		
Number Accepted or Passed TS on First Cycle	17	17	4		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted or Failed TS on First Cycle	5	2	1		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	22.73%	10.53%	20.00%		

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 8.2 OHT7 - Office of In Vitro Diagnostics  
De Novo MDUFA V Decision Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	20	18	4		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	20	12	0		
MDUFA Decision Within 150 FDA Days	20	12	0		
De Novos Pending MDUFA Decision	0	6	4		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	N/A		

**Table 8.3 OHT7 - Office of In Vitro Diagnostics  
De Novo Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.60	1.42	N/A		
Number With MDUFA Decision	20	12	0		
Average FDA Days to MDUFA Decision	127.95	113.08	N/A		
20th Percentile FDA Days to MDUFA Decision	85	73	0		
40th Percentile FDA Days to MDUFA Decision	140	94	0		
60th Percentile FDA Days to MDUFA Decision	149	141	0		



80th Percentile FDA Days to MDUFA Decision	150	150	0		
Maximum FDA Days to MDUFA Decision	150	150	0		
<b>Average Industry Days to MDUFA Decision</b>	167.85	89.50	N/A		
20th Percentile Industry Days to MDUFA Decision	139	0	0		
40th Percentile Industry Days to MDUFA Decision	175	44	0		
60th Percentile Industry Days to MDUFA Decision	179	137	0		
80th Percentile Industry Days to MDUFA Decision	182	181	0		
Maximum Industry Days to MDUFA Decision	350	185	0		
<b>Average Total Days to MDUFA Decision</b>	295.80	202.58	N/A		
20th Percentile Total Days to MDUFA Decision	252	124	0		
40th Percentile Total Days to MDUFA Decision	299	194	0		
60th Percentile Total Days to MDUFA Decision	328	247	0		
80th Percentile Total Days to MDUFA Decision	330	259	0		
Maximum Total Days to MDUFA Decision	437	328	0		

**Table 8.4 OHT7 - Office of In Vitro Diagnostics**

**De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
De Novos Accepted	20	18	4		
Number With MDUFA Decision	20	12	0		
Number With Granted Decision	5	6	0		
Number With Declined Decision	5	1	0		
Number of Withdrawal	9	2	0		
Number of Deleted	1	3	0		
Rate of Granted Decision	25.00%	50.00%	N/A		
Rate of Declined Decision	25.00%	8.33%	N/A		
Rate of Withdrawal	45.00%	16.67%	N/A		
Rate of Deleted	5.00%	25.00%	N/A		



**Table 8.5 OHT7 - Office of In Vitro Diagnostics**  
**De Novo Performance Metrics-Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A	N/A		

**Table 8.6 OHT7 - Office of In Vitro Diagnostics**  
**LDT De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	1	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	1	0	0		
MDUFA Decision Within 150 FDA Days	1	0	0		
De Novos Pending MDUFA V Decision	0	0	0		
De Novos Pending MDUFA V Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	N/A	N/A		

**Table 8.7 OHT7 - Office of In Vitro Diagnostics**  
**Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	19	18	4		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	19	12	0		
MDUFA Decision Within 150 FDA Days	19	12	0		
De Novos Pending MDUFA V Decision	0	6	4		
De Novos Pending MDUFA V Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	N/A		



## Section 8 - De Novo Office Level Metrics

**Table 8.1 OHT8 - Office of Radiological Health  
De Novo Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	5	2		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	4	4	2		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted or Failed TS on First Cycle	0	1	0		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	0.00%	20.00%	0.00%		

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 8.2 OHT8 - Office of Radiological Health  
De Novo MDUFA V Decision Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	4	4	2		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	4	2	0		
MDUFA Decision Within 150 FDA Days	4	2	0		
De Novos Pending MDUFA Decision	0	2	2		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	N/A		

**Table 8.3 OHT8 - Office of Radiological Health  
De Novo Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.25	1.50	N/A		
Number With MDUFA Decision	4	2	0		
Average FDA Days to MDUFA Decision	108.75	124.00	N/A		
20th Percentile FDA Days to MDUFA Decision	70	115	0		
40th Percentile FDA Days to MDUFA Decision	89	121	0		
60th Percentile FDA Days to MDUFA Decision	133	127	0		



80th Percentile FDA Days to MDUFA Decision	149	133	0		
Maximum FDA Days to MDUFA Decision	150	139	0		
<b>Average Industry Days to MDUFA Decision</b>	130.50	88.00	N/A		
20th Percentile Industry Days to MDUFA Decision	83	35	0		
40th Percentile Industry Days to MDUFA Decision	132	70	0		
60th Percentile Industry Days to MDUFA Decision	169	106	0		
80th Percentile Industry Days to MDUFA Decision	186	141	0		
Maximum Industry Days to MDUFA Decision	193	176	0		
<b>Average Total Days to MDUFA Decision</b>	239.25	212.00	N/A		
20th Percentile Total Days to MDUFA Decision	190	150	0		
40th Percentile Total Days to MDUFA Decision	258	191	0		
60th Percentile Total Days to MDUFA Decision	265	233	0		
80th Percentile Total Days to MDUFA Decision	297	274	0		
Maximum Total Days to MDUFA Decision	343	315	0		

**Table 8.4 OHT8 - Office of Radiological Health  
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	4	4	2		
Number With MDUFA Decision	4	2	0		
Number With Granted Decision	2	0	0		
Number With Declined Decision	0	1	0		
Number of Withdrawal	1	1	0		
Number of Deleted	1	0	0		
Rate of Granted Decision	50.00%	0.00%	N/A		
Rate of Declined Decision	0.00%	50.00%	N/A		
Rate of Withdrawal	25.00%	50.00%	N/A		
Rate of Deleted	25.00%	0.00%	N/A		



**Table 8.5 OHT8 - Office of Radiological Health**  
**De Novo Performance Metrics-Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A	N/A		

**Table 8.6 OHT8 - Office of Radiological Health**  
**LDT De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA V Decision	0	0	0		
De Novos Pending MDUFA V Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		

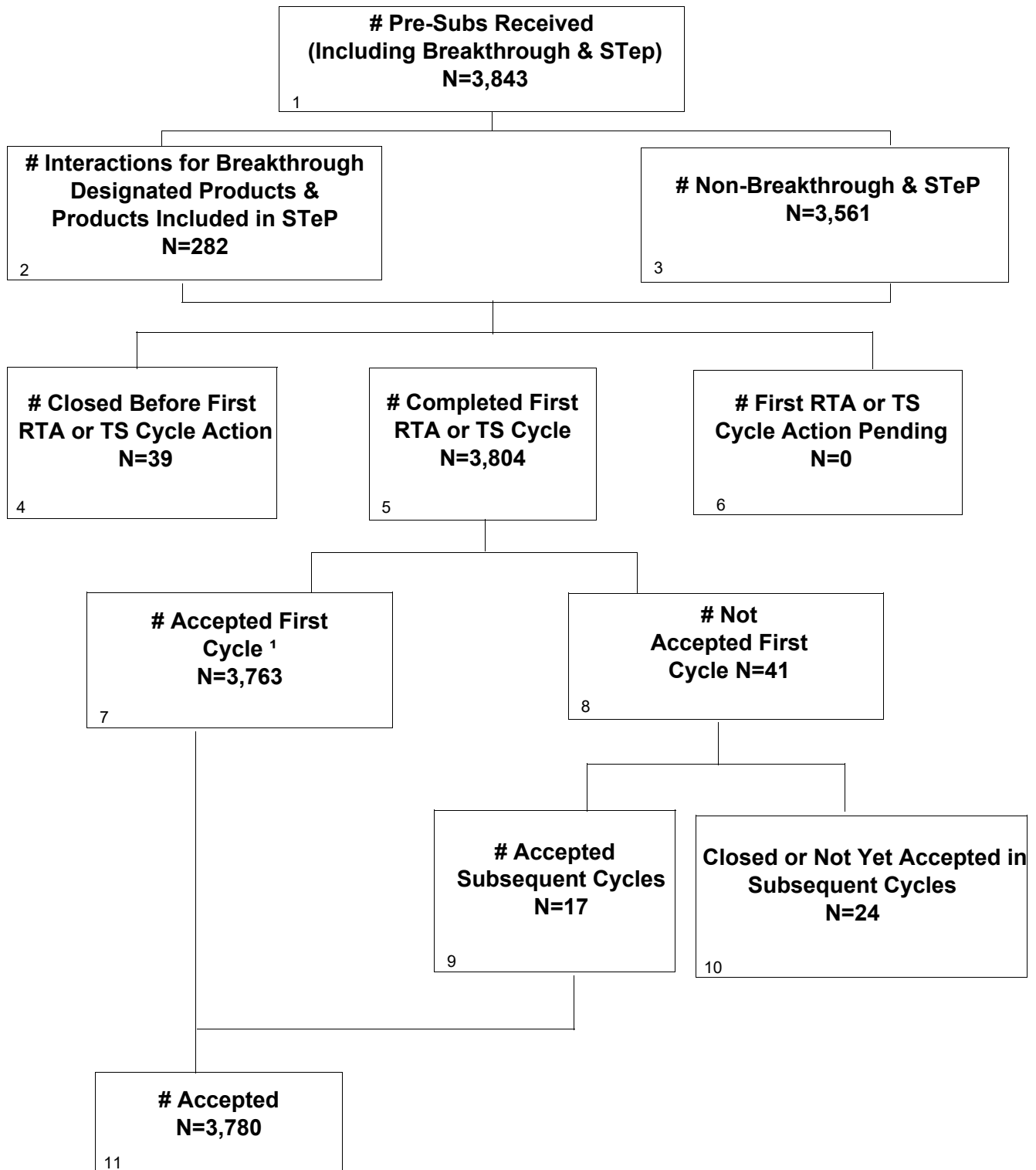
**Table 8.7 OHT8 - Office of Radiological Health**  
**Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA V Decision	0	0	0		
De Novos Pending MDUFA V Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		



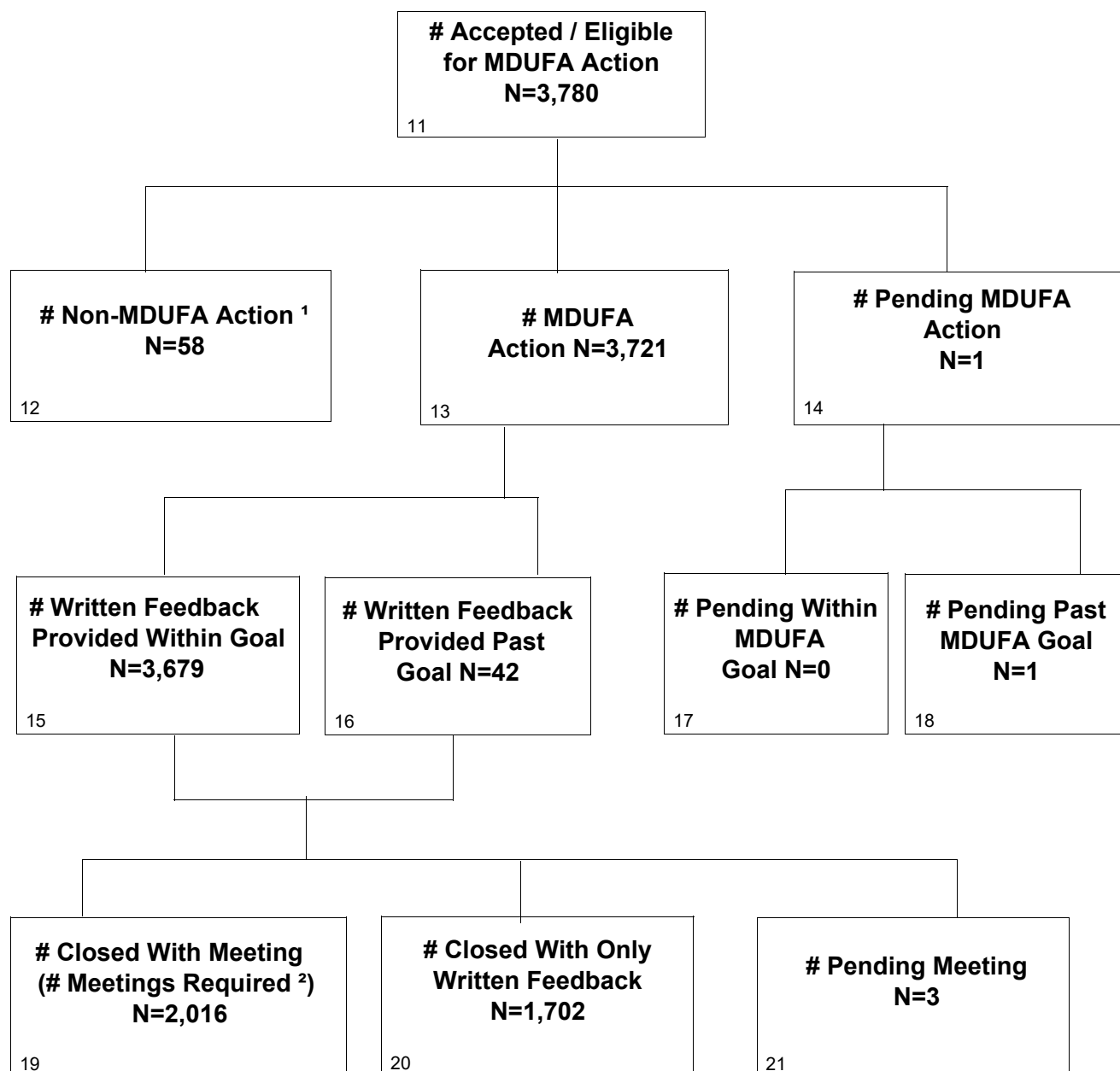
# CDRH Pre-Sub - FY 2023

## as of 3/31/25





# CDRH Pre-Sub - FY 2023 as of 3/31/25 Continued

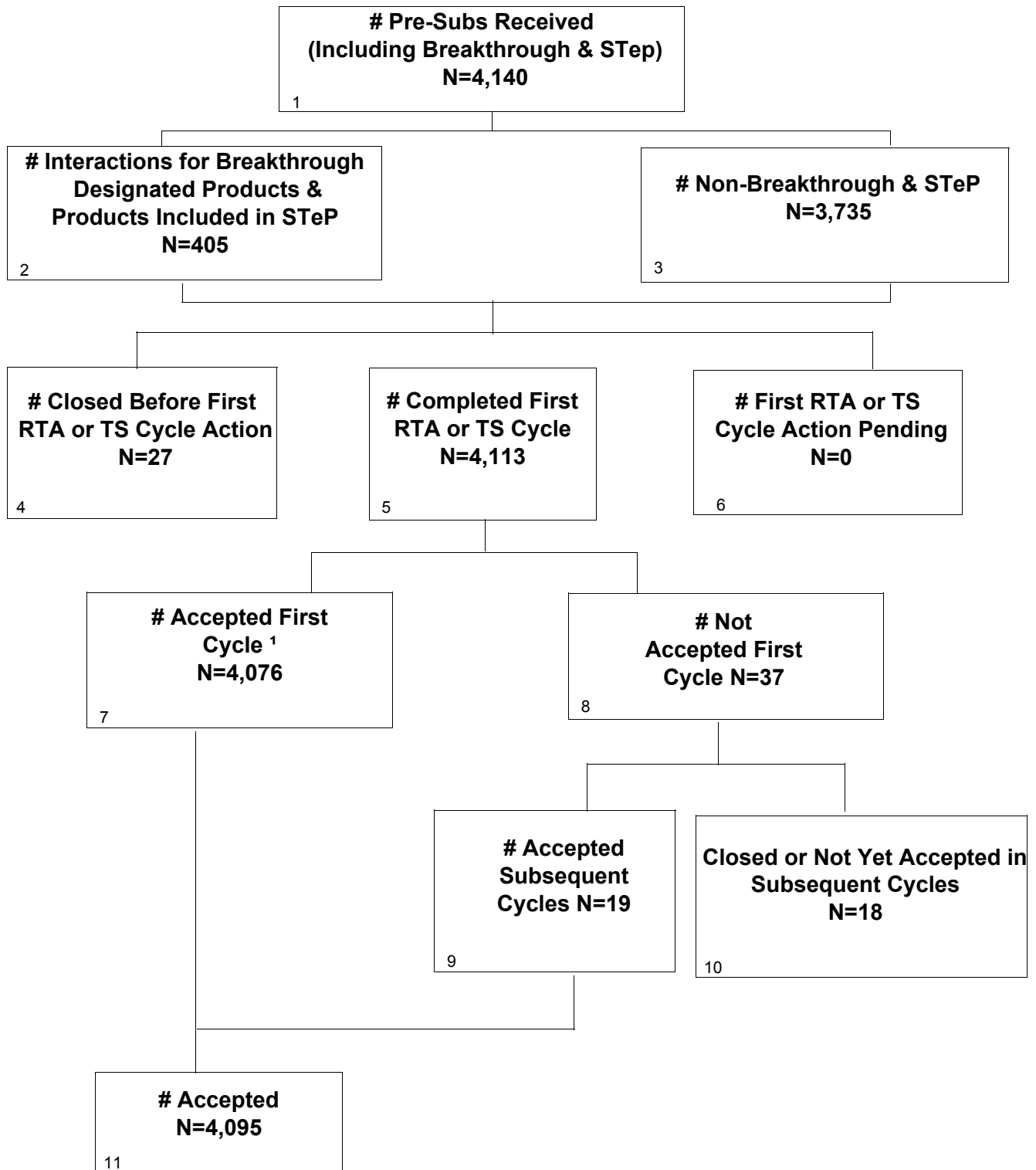


1. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

2. Number of meetings requested and then held after written feedback is provided.



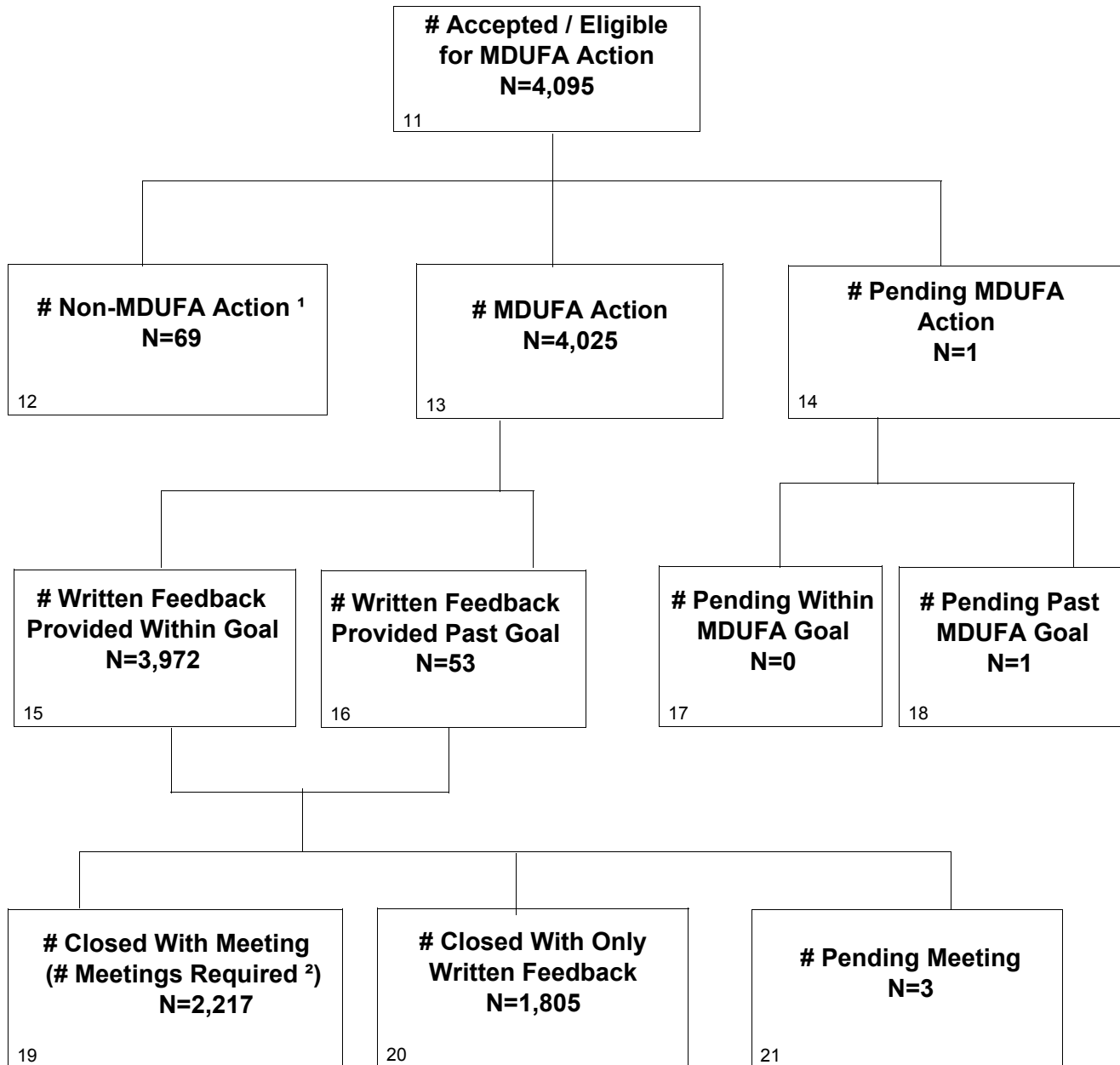
# CDRH Pre-Sub - FY 2024 as of 3/31/25



1. This includes submissions accepted or passed TS on first cycle, submissions without a first cycle RTA or TS review, and those considered accepted upon receipt.



# CDRH Pre-Sub - FY 2024 as of 3/31/25 Continued



1. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

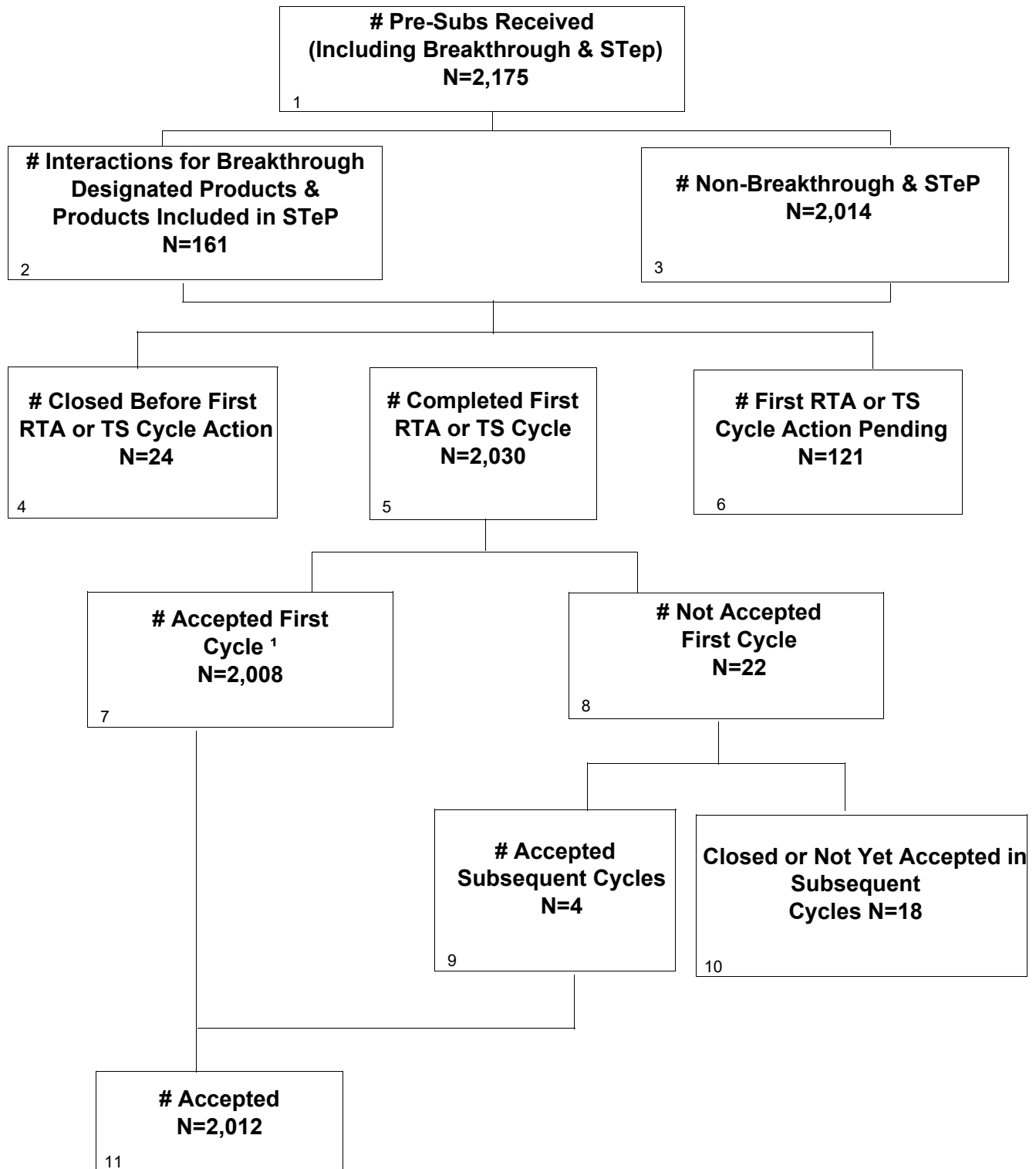
2. Number of meetings requested and then held after written feedback is provided.



# CDRH Pre-Sub - FY 2025

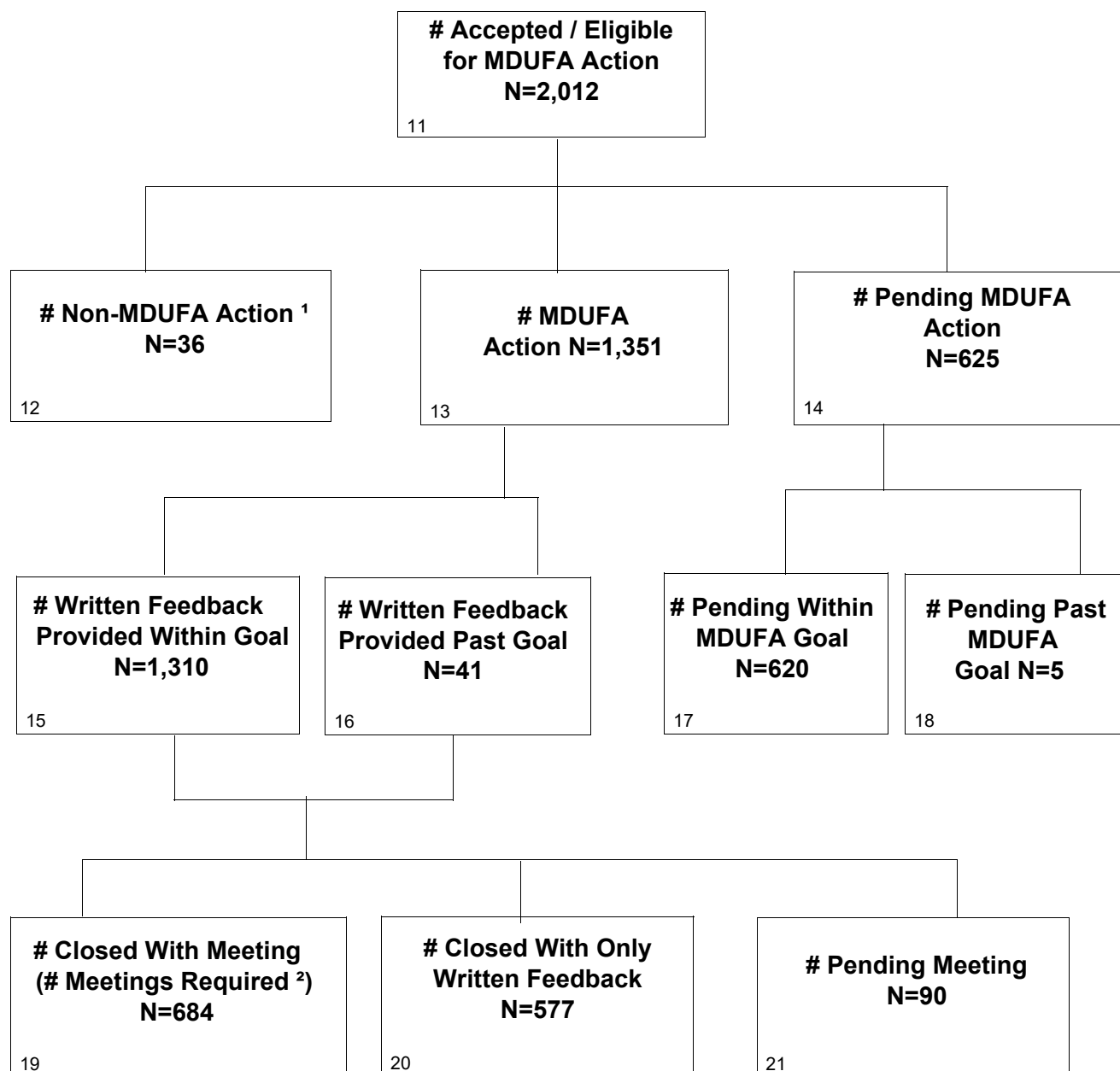
## as of 3/31/25

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# CDRH Pre-Sub - FY 2025 as of 12/31/24 Continued



1. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

2. Number of meetings requested and then held after written feedback is provided.



## Section 9 Pre-Sub Center Level Metrics

**Table 9.1 CDRH - Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3,843	4,140	2,175		
Interactions for Breakthrough Designated Products & Products Included in STeP	282	405	161		
Number Closed Before First RTA Action	39	27	24		
Number Accepted First RTA Cycle <sup>1</sup>	3,642	3,979	1,932		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	121	97	76		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	121		
Number Not Accepted First RTA Cycle	41	37	22		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.08%	0.90%	1.08%		

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

**Table 9.2 CDRH - MDUFA V Pre-Sub Performance Goals**

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	3,780	4,095	2,012		
Number with Non-MDUFA Action <sup>3</sup>	58	69	36		
Number with MDUFA Action	3,721	4,025	1,351		
Written Feedback Provided Within Goal	3,679	3,972	1,310		
Number Pending MDUFA Action	1	1	625		
Pending MDUFA Action Past Goal	1	1	5		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	3,722	4,026	1,976		
Current Performance Percent Within Goal	98.84%	98.66%	96.61%		

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.



**Table 9.3 CDRH – MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	3,721	4,025	1,351		
Average FDA Days to Written Feedback	62.20	62.25	61.18		
20th Percentile FDA Days to Written Feedback	56	56	55		
40th Percentile FDA Days to Written Feedback	64	64	63		
60th Percentile FDA Days to Written Feedback	68	67	67		
80th Percentile FDA Days to Written Feedback	70	70	70		
Maximum FDA Days to Written Feedback	141	245	89		

**Table 9.4 CDRH - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling  
(for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	136	130	60		
Average Days to Scheduling for Meetings Scheduled After Day 30	41.52	40.57	39.77		

**Table 9.5 CDRH - MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required <sup>1</sup>	2,015	2,217	684		
Meeting Minutes Submitted Within 15 Days of Meeting	1,531	1,786	524		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	40		
Meeting Minutes Past 15 Days of Meeting	434	366	96		
Meeting Minutes Not Submitted and >15 Days Since Meeting	50	65	24		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.98%	80.56%	81.37%		

1. Number of meetings requested and then held after written feedback is provided.



## Section 9 Pre-Sub Office Level Metrics

**Table 9.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	444	493	258		
Interactions for Breakthrough Designated Products & Products Included in STeP	20	27	9		
Number Closed Before First RTA Action	4	6	2		
Number Accepted First RTA Cycle <sup>1</sup>	411	462	230		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	20	20	5		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	14		
Number Not Accepted First RTA Cycle	9	5	7		
Rate of Submissions Not Accepted for Review on First RTA Cycle	2.05%	1.03%	2.89%		

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

**Table 9.2 OHT1 -Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
MDUFA V Pre-Sub Performance Goals**

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	435	486	237		
Number with Non-MDUFA Action <sup>3</sup>	12	12	6		
Number with MDUFA Action	423	474	148		
Written Feedback Provided Within Goal	410	461	144		
Number Pending MDUFA Action	0	0	83		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	423	474	231		
Current Performance Percent Within Goal	96.93%	97.26%	97.30%		

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.



**Table 9.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	423	474	148		
Average FDA Days to Written Feedback	65.34	65.27	63.70		
20th Percentile FDA Days to Written Feedback	62	62	59		
40th Percentile FDA Days to Written Feedback	66	66	66		
60th Percentile FDA Days to Written Feedback	69	69	69		
80th Percentile FDA Days to Written Feedback	70	70	70		
Maximum FDA Days to Written Feedback	141	101	81		

**Table 9.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	30	23	13		
Average Days to Scheduling for Meetings Scheduled After Day 30	48.47	42.70	38.00		

**Table 9.5 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device  
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required <sup>1</sup>	249	276	80		
Meeting Minutes Submitted Within 15 Days of Meeting	179	227	56		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	3		
Meeting Minutes Past 15 Days of Meeting	59	38	14		
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	11	7		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.89%	82.25%	72.73%		

**1. Number of meetings requested and then held after written feedback is provided.**



**Table 9.1 OHT2 - Office of Cardiovascular Devices**  
**Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	722	745	383		
Interactions for Breakthrough Designated Products & Products Included in STeP	73	84	30		
Number Closed Before First RTA Action	6	2	2		
Number Accepted First RTA Cycle <sup>1</sup>	699	726	343		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	13	14	16		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	21		
Number Not Accepted First RTA Cycle	4	3	1		
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.56%	0.40%	0.28%		

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

**Table 9.2 OHT2 - Office of Cardiovascular Devices**  
**MDUFA V Pre-Sub Performance Goals**

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	715	741	359		
Number with Non-MDUFA Action <sup>3</sup>	4	4	3		
Number with MDUFA Action	710	736	236		
Written Feedback Provided Within Goal	695	715	215		
Number Pending MDUFA Action	1	1	120		
Pending MDUFA Action Past Goal	1	1	1		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	711	737	356		
Current Performance Percent Within Goal	97.75%	97.01%	90.72%		

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.



**Table 9.3 OHT2 - Office of Cardiovascular Devices****MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	710	736	236		
Average FDA Days to Written Feedback	59.30	59.66	58.92		
20th Percentile FDA Days to Written Feedback	50	51	50		
40th Percentile FDA Days to Written Feedback	60	61	59		
60th Percentile FDA Days to Written Feedback	66	65	65		
80th Percentile FDA Days to Written Feedback	69	69	70		
Maximum FDA Days to Written Feedback	103	113	89		

**Table 9.4 OHT2 - Office of Cardiovascular Devices****MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	32	21	12		
Average Days to Scheduling for Meetings Scheduled After Day 30	38.19	36.90	35.75		

**Table 9.5 OHT2 - Office of Cardiovascular Devices****MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required <sup>1</sup>	404	424	122		
Meeting Minutes Submitted Within 15 Days of Meeting	306	318	90		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	9		
Meeting Minutes Past 15 Days of Meeting	91	90	16		
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	16	7		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.74%	75.00%	79.65%		

1. Number of meetings requested and then held after written feedback is provided.



**Table 9.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	461	509	279		
Interactions for Breakthrough Designated Products & Products Included in STeP	42	63	26		
Number Closed Before First RTA Action	5	4	5		
Number Accepted First RTA Cycle <sup>1</sup>	438	483	238		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	12	11	8		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	23		
Number Not Accepted First RTA Cycle	6	11	5		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.32%	2.18%	1.99%		

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

**Table 9.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
MDUFA V Pre-Sub Performance Goals**

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	453	498	247		
Number with Non-MDUFA Action <sup>3</sup>	10	11	2		
Number with MDUFA Action	443	487	165		
Written Feedback Provided Within Goal	439	484	162		
Number Pending MDUFA Action	0	0	80		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	443	487	245		
Current Performance Percent Within Goal	99.10%	99.38%	98.18%		

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.



**Table 9.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	443	487	165		
Average FDA Days to Written Feedback	62.12	61.72	62.18		
20th Percentile FDA Days to Written Feedback	56	56	57		
40th Percentile FDA Days to Written Feedback	64	63	63		
60th Percentile FDA Days to Written Feedback	67	67	67		
80th Percentile FDA Days to Written Feedback	70	70	69		
Maximum FDA Days to Written Feedback	78	78	79		

**Table 9.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	13	12	5		
Average Days to Scheduling for Meetings Scheduled After Day 30	41.85	43.50	42.80		

**Table 9.5 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices  
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required <sup>1</sup>	255	267	79		
Meeting Minutes Submitted Within 15 Days of Meeting	200	221	69		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	5		
Meeting Minutes Past 15 Days of Meeting	49	39	4		
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	7	1		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.43%	82.77%	93.24%		

**1. Number of meetings requested and then held after written feedback is provided.**



**Table 9.1 OHT4 - Office of Surgical and Infection Control Devices**  
**Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	383	465	281		
Interactions for Breakthrough Designated Products & Products Included in STeP	21	35	17		
Number Closed Before First RTA Action	4	5	5		
Number Accepted First RTA Cycle <sup>1</sup>	363	438	246		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	9	14	20		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	10		
Number Not Accepted First RTA Cycle	7	8	0		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.85%	1.74%	0.00%		

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

**Table 9.2 OHT4 - Office of Surgical and Infection Control Devices**  
**MDUFA V Pre-Sub Performance Goals**

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	375	457	266		
Number with Non-MDUFA Action <sup>3</sup>	11	18	8		
Number with MDUFA Action	364	439	176		
Written Feedback Provided Within Goal	364	437	171		
Number Pending MDUFA Action	0	0	82		
Pending MDUFA Action Past Goal	0	0	1		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	364	439	258		
Current Performance Percent Within Goal	100.00%	99.54%	96.61%		

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.



**Table 9.3 OHT4 - Office of Surgical and Infection Control Devices****MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	364	439	176		
Average FDA Days to Written Feedback	60.57	61.87	58.90		
20th Percentile FDA Days to Written Feedback	55	56	50		
40th Percentile FDA Days to Written Feedback	62	63	60		
60th Percentile FDA Days to Written Feedback	65	67	65		
80th Percentile FDA Days to Written Feedback	69	70	69		
Maximum FDA Days to Written Feedback	70	70	85		

**Table 9.4 OHT4 - Office of Surgical and Infection Control Devices****MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	15	15	8		
Average Days to Scheduling for Meetings Scheduled After Day 30	37.53	40.00	40.38		

**Table 9.5 OHT4 - Office of Surgical and Infection Control Devices****MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required <sup>1</sup>	208	235	97		
Meeting Minutes Submitted Within 15 Days of Meeting	161	183	73		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	4		
Meeting Minutes Past 15 Days of Meeting	39	48	18		
Meeting Minutes Not Submitted and >15 Days Since Meeting	8	4	2		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.40%	77.87%	78.49%		

1. Number of meetings requested and then held after written feedback is provided.



**Table 9.1 OHT5 - Office of Neurological and Physical Medicine Devices  
Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	396	426	208		
Interactions for Breakthrough Designated Products & Products Included in STeP	42	42	20		
Number Closed Before First RTA Action	5	3	1		
Number Accepted First RTA Cycle <sup>1</sup>	370	404	177		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	17	10	6		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	17		
Number Not Accepted First RTA Cycle	4	9	7		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.02%	2.13%	3.68%		

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

**Table 9.2 OHT5 - Office of Neurological and Physical Medicine Devices  
MDUFA V Pre-Sub Performance Goals**

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	389	419	184		
Number with Non-MDUFA Action <sup>3</sup>	5	5	3		
Number with MDUFA Action	384	414	131		
Written Feedback Provided Within Goal	382	406	126		
Number Pending MDUFA Action	0	0	50		
Pending MDUFA Action Past Goal	0	0	3		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	384	414	181		
Current Performance Percent Within Goal	99.48%	98.07%	94.03%		

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.



**Table 9.3 OHT5 - Office of Neurological and Physical Medicine Devices**  
**MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	384	414	131		
Average FDA Days to Written Feedback	66.14	67.29	64.75		
20th Percentile FDA Days to Written Feedback	64	65	62		
40th Percentile FDA Days to Written Feedback	68	69	67		
60th Percentile FDA Days to Written Feedback	70	70	70		
80th Percentile FDA Days to Written Feedback	70	70	70		
Maximum FDA Days to Written Feedback	108	245	78		

**Table 9.4 CDRH- OHT5 - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	25	39	10		
Average Days to Scheduling for Meetings Scheduled After Day 30	39.32	39.26	36.10		

**Table 9.5 OHT5 - Office of Neurological and Physical Medicine Devices**  
**MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required <sup>1</sup>	249	257	69		
Meeting Minutes Submitted Within 15 Days of Meeting	178	205	53		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	5		
Meeting Minutes Past 15 Days of Meeting	64	43	8		
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	9	3		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.49%	79.77%	82.81%		

**1. Number of meetings requested and then held after written feedback is provided.**



**Table 9.1 OHT6 - Office of Orthopedic Devices  
Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	288	294	146		
Interactions for Breakthrough Designated Products & Products Included in STeP	52	79	23		
Number Closed Before First RTA Action	5	1	1		
Number Accepted First RTA Cycle <sup>1</sup>	269	286	131		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	10	7	4		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	9		
Number Not Accepted First RTA Cycle	4	0	1		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.41%	0.00%	0.74%		

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

**Table 9.2 OHT6 - Office of Orthopedic Devices  
MDUFA V Pre-Sub Performance Goals**

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	281	293	135		
Number with Non-MDUFA Action <sup>3</sup>	6	8	7		
Number with MDUFA Action	275	285	93		
Written Feedback Provided Within Goal	271	280	93		
Number Pending MDUFA Action	0	0	35		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	275	285	128		
Current Performance Percent Within Goal	98.55%	98.25%	100.00%		

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.



**Table 9.3 OHT6 - Office of Orthopedic Devices****MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	275	285	93		
Average FDA Days to Written Feedback	58.44	56.93	58.54		
20th Percentile FDA Days to Written Feedback	45	43	45		
40th Percentile FDA Days to Written Feedback	58	57	60		
60th Percentile FDA Days to Written Feedback	65	64	65		
80th Percentile FDA Days to Written Feedback	69	68	68		
Maximum FDA Days to Written Feedback	97	92	70		

**Table 9.4 CDRH- OHT6 - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	4	2	3		
Average Days to Scheduling for Meetings Scheduled After Day 30	48.75	54.50	35.00		

**Table 9.5 OHT6 - Office of Orthopedic Devices****MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required <sup>1</sup>	124	129	42		
Meeting Minutes Submitted Within 15 Days of Meeting	91	103	27		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	5		
Meeting Minutes Past 15 Days of Meeting	29	17	9		
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	9	1		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	73.39%	79.84%	72.97%		

1. Number of meetings requested and then held after written feedback is provided.



**Table 9.1 OHT7 - Office of In Vitro Diagnostics  
Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	880	922	460		
Interactions for Breakthrough Designated Products & Products Included in STeP	28	60	28		
Number Closed Before First RTA Action	9	5	7		
Number Accepted First RTA Cycle <sup>1</sup>	833	901	415		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	35	15	15		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	23		
Number Not Accepted First RTA Cycle	3	1	0		
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.34%	0.11%	0.00%		

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

**Table 9.2 OHT7 - Office of In Vitro Diagnostics  
MDUFA V Pre-Sub Performance Goals**

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	868	916	430		
Number with Non-MDUFA Action <sup>3</sup>	7	11	5		
Number with MDUFA Action	861	905	290		
Written Feedback Provided Within Goal	857	904	288		
Number Pending MDUFA Action	0	0	135		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	861	905	425		
Current Performance Percent Within Goal	99.54%	99.89%	99.31%		

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.



**Table 9.3 OHT7 - Office of In Vitro Diagnostics****MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	861	905	290		
Average FDA Days to Written Feedback	63.70	63.11	61.81		
20th Percentile FDA Days to Written Feedback	60	59	56		
40th Percentile FDA Days to Written Feedback	66	65	64		
60th Percentile FDA Days to Written Feedback	69	68	67		
80th Percentile FDA Days to Written Feedback	70	70	70		
Maximum FDA Days to Written Feedback	75	71	89		

**Table 9.4 OHT7 - Office of In Vitro Diagnostics****MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	12	14	8		
Average Days to Scheduling for Meetings Scheduled After Day 30	38.83	41.00	50.75		

**Table 9.5 OHT7 - Office of In Vitro Diagnostics****MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required <sup>1</sup>	320	415	126		
Meeting Minutes Submitted Within 15 Days of Meeting	257	356	100		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	5		
Meeting Minutes Past 15 Days of Meeting	59	53	19		
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	6	2		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	80.31%	85.78%	82.64%		

1. Number of meetings requested and then held after written feedback is provided.



**Table 9.1 OHT8 - Office of Radiological Health  
Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	269	286	160		
Interactions for Breakthrough Designated Products & Products Included in STeP	4	15	8		
Number Closed Before First RTA Action	1	1	1		
Number Accepted First RTA Cycle <sup>1</sup>	259	279	152		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	5	6	2		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	4		
Number Not Accepted First RTA Cycle	4	0	1		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.49%	0.00%	0.65%		

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

**Table 9.2 OHT8 - Office of Radiological Health  
MDUFA V Pre-Sub Performance Goals**

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	264	285	154		
Number with Non-MDUFA Action <sup>3</sup>	3	0	2		
Number with MDUFA Action	261	285	112		
Written Feedback Provided Within Goal	261	285	111		
Number Pending MDUFA Action	0	0	40		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	261	285	152		
Current Performance Percent Within Goal	100.00%	100.00%	99.11%		

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.



**Table 9.3 OHT8 - Office of Radiological Health****MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	261	285	112		
Average FDA Days to Written Feedback	60.57	60.68	61.16		
20th Percentile FDA Days to Written Feedback	55	55	56		
40th Percentile FDA Days to Written Feedback	60	62	62		
60th Percentile FDA Days to Written Feedback	64	65	65		
80th Percentile FDA Days to Written Feedback	67	69	69		
Maximum FDA Days to Written Feedback	70	70	71		

**Table 9.4 OHT8 - Office of Radiological Health****MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	5	4	1		
Average Days to Scheduling for Meetings Scheduled After Day 30	44.00	45.25	54.00		

**Table 9.5 OHT8 - Office of Radiological Health****MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)**

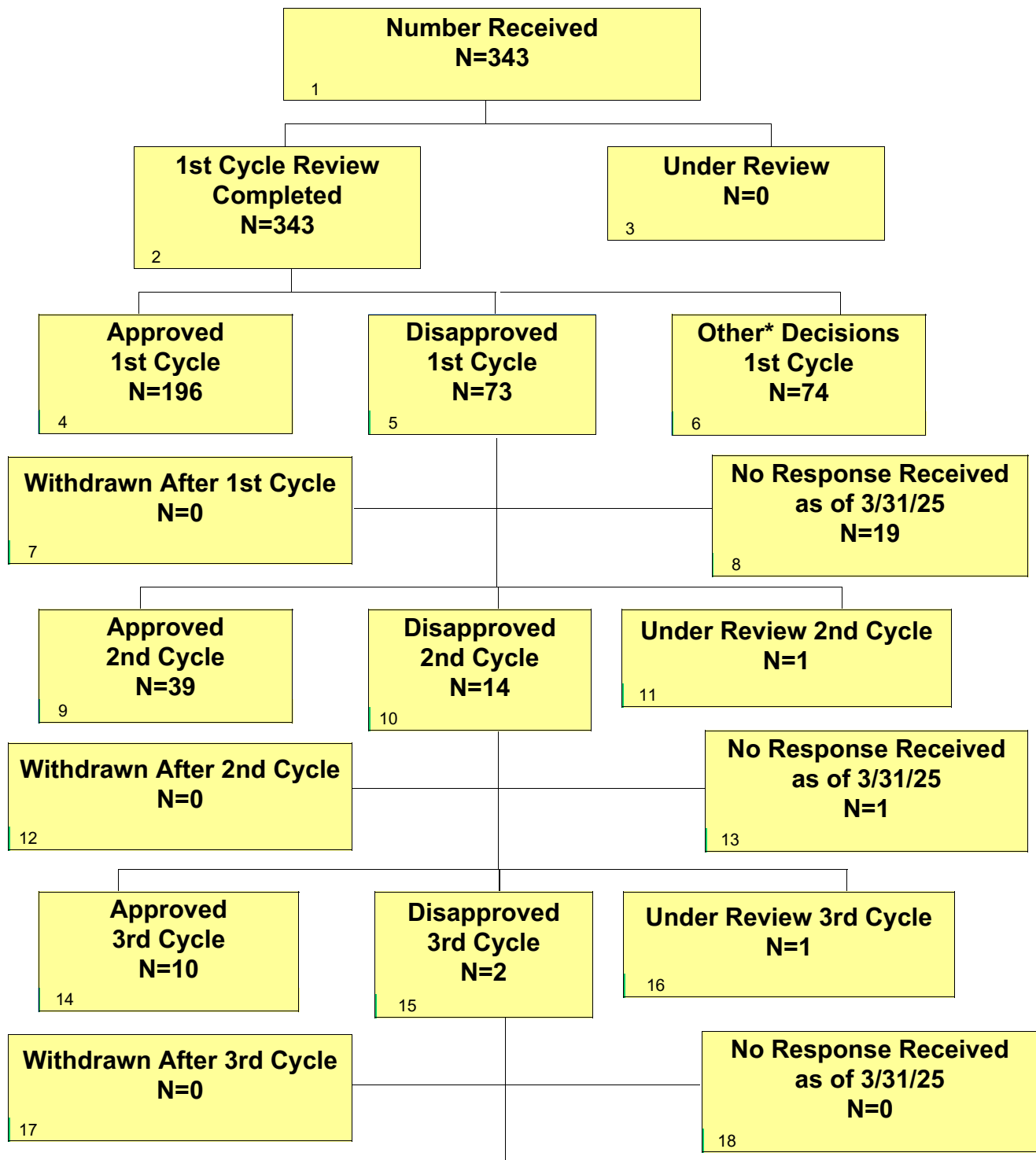
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required <sup>1</sup>	206	214	69		
Meeting Minutes Submitted Within 15 Days of Meeting	159	173	56		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	4		
Meeting Minutes Past 15 Days of Meeting	44	38	8		
Meeting Minutes Not Submitted and >15 Days Since Meeting	3	3	1		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.18%	80.84%	86.15%		

1. Number of meetings requested and then held after written feedback is provided.



# CDRH IDEs - FY 2023

## as of 3/31/25



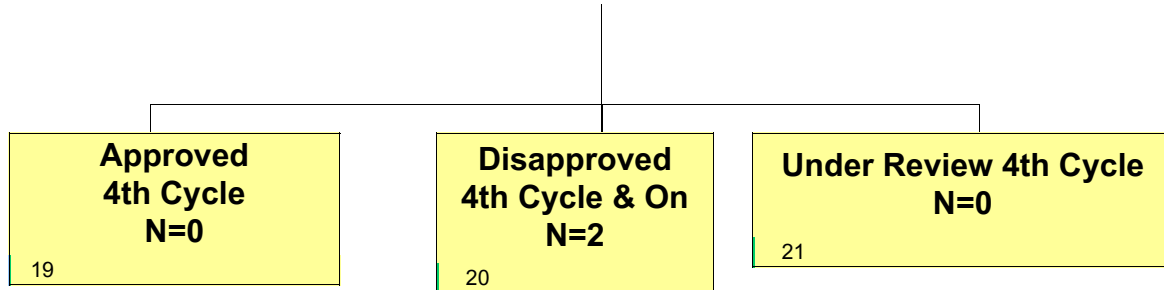
\* Other decisions include withdrawn (N=11), withdrawn and converted (N=51), RTA (N=0), nonsignificant risk device (N=10), exempt (N=0), product jurisdiction pending (N=1), or product jurisdiction transferred (N=1), Basic Physiological Research (N=0).



# CDRH IDEs - FY 2023

## as of 3/31/25

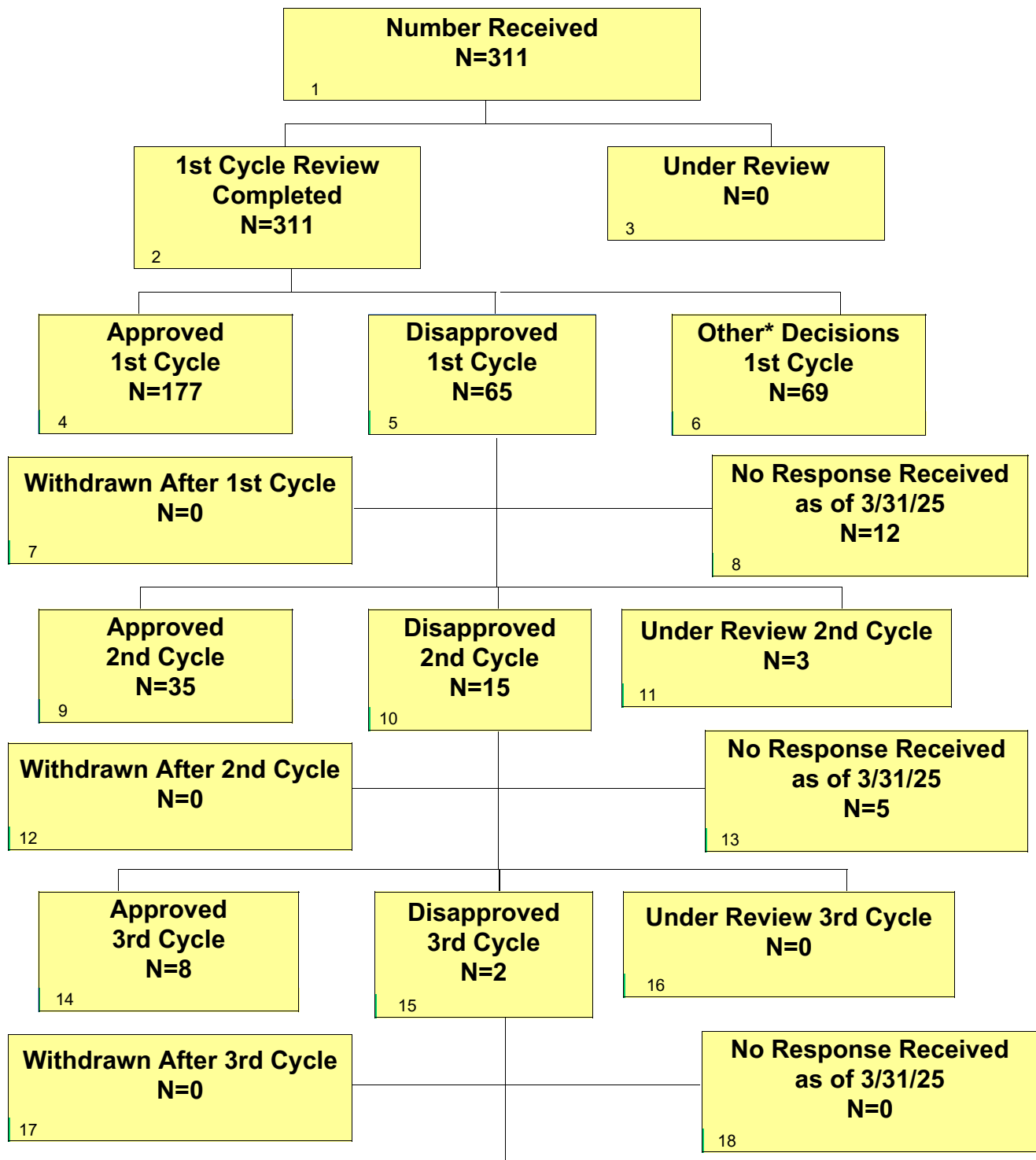
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# CDRH IDEs - FY 2024

## as of 3/31/25



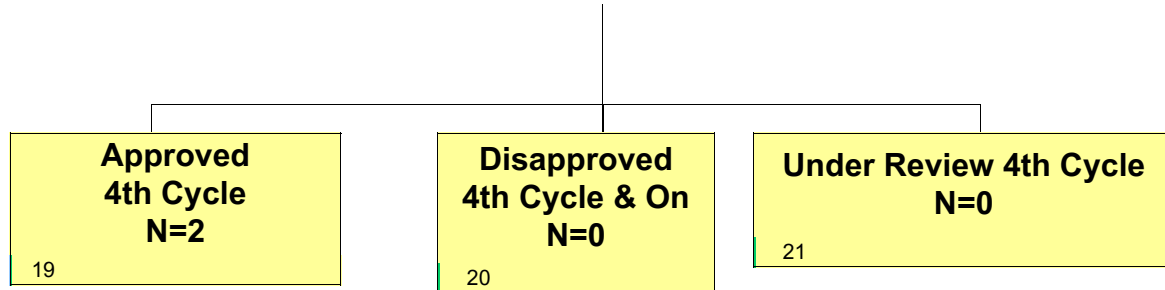
\* Other decisions include withdrawn (N=9), withdrawn and converted (N=35), RTA (N=0), nonsignificant risk device (N=16), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=9), Basic Physiological Research (N=0).



# CDRH IDEs - FY 2024

## as of 3/31/25

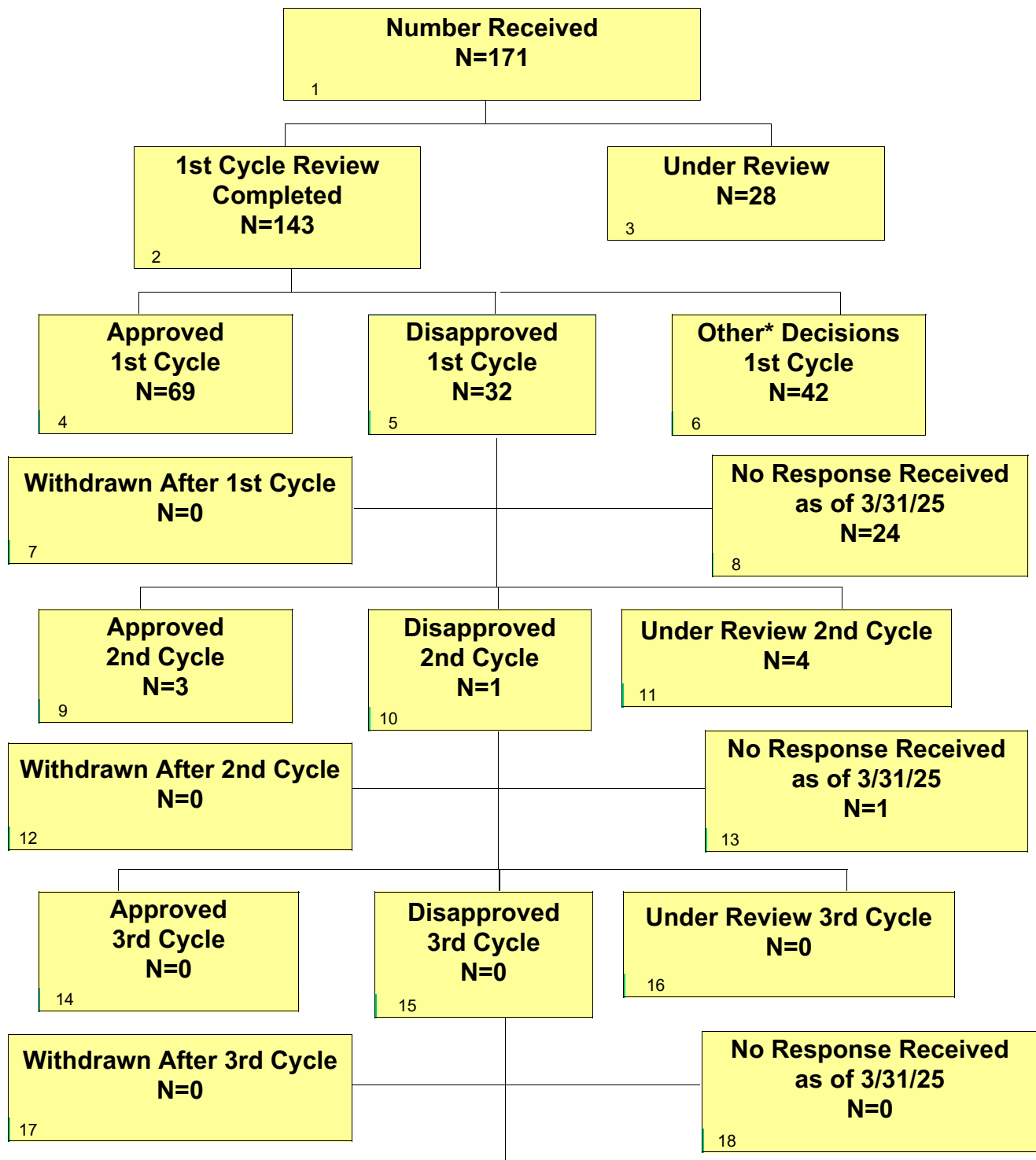
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# CDRH IDEs - FY 2025

## as of 3/31/25



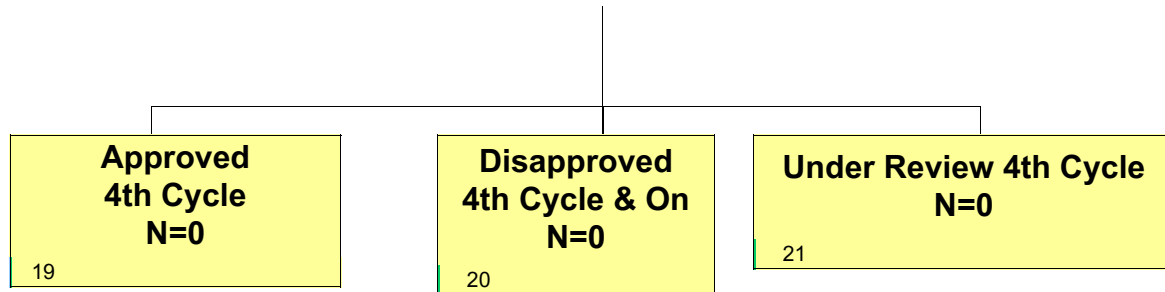
\* Other decisions include withdrawn (N=8), withdrawn and converted (N=22), RTA (N=0), nonsignificant risk device (N=9), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=2), Basic Physiological Research (N=0).



# CDRH IDEs - FY 2025

## as of 3/31/25

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Section 10 IDE- Center Level Metric

Table 10.1 CDRH - IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	343	311	171		
Average Number of Cycles to IDE Approval or Conditional Approval	1.27	1.26	1.04		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.27	0.26	0.04		



Section 10 IDE - Office Level Metric

Table 10.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices  
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	42	32	12		
Average Number of Cycles to IDE Approval or Conditional Approval	1.37	1.21	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.37	0.21	0.00		

Section 10 IDE - Office Level Metric

Table 10.1 OHT2 - Office of Cardiovascular Devices  
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	74	81	39		
Average Number of Cycles to IDE Approval or Conditional Approval	1.48	1.36	1.10		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.48	0.36	0.10		

Section 10 IDE - Office Level Metric

Table 10.1 OHT3 - Office of Gastorenal, ObGyn, General Hospital, and Urology Devices  
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	35	41	20		
Average Number of Cycles to IDE Approval or Conditional Approval	1.29	1.29	1.14		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.29	0.29	0.14		

Section 10 IDE - Office Level Metric

Table 10.1 OHT4 - Office of Surgical and Infection Control Devices  
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	38	17	22		
Average Number of Cycles to IDE Approval or Conditional Approval	1.10	1.00	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.10	0.00	0.00		

Section 10 IDE - Office Level Metric

Table 10.1 OHT5 - Office of Neurological and Physical Medicine Devices  
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	74	63	46		
Average Number of Cycles to IDE Approval or Conditional Approval	1.23	1.38	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.23	0.38	0.00		



Section 10 IDE - Office Level Metric

Table 10.1 OHT6 - Office of Orthopedic Devices  
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	26	23	11		
Average Number of Cycles to IDE Approval or Conditional Approval	1.33	1.27	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.33	0.27	0.00		

Section 10 IDE - Office Level Metric

Table 10.1 OHT7 - Office of In Vitro Diagnostics  
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	46	43	18		
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.00	0.00		

Section 10 IDE - Office Level Metric

Table 10.1 OHT8 - Office of Radiological Health  
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	8	11	3		
Average Number of Cycles to IDE Approval or Conditional Approval	1.40	1.25	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.40	0.25	0.00		



## **Section 11      CLIA Waiver Annual Metrics**

CLIA Waiver Annual Metrics and Goals will be reported in the Annual Report.



## **Section 12 Dual (510(k) and CLIA Waiver) Annual Metrics**

Dual (510(k) and CLIA Waiver) Annual Metrics and Goals will be reported in the Annual Report.



Section 13 TAP Center Level Metrics

Table 13.1 CDRH - TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		31	29		
Closed before Teleconference		0	0		
Teleconferences Held		31	25		
Teleconferences Held Within 14 Days		30	24		
Teleconferences Pending		0	4		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		96.77%	96.00%		

Table 13.2 CDRH - TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		3	6		
Closed before Written Feedback		0	0		
Written Feedback Provided		3	6		
Written Feedback Provided Within 21 Days		3	5		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		100.00%	83.33%		

Table 13.3 CDRH - TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		44	25		
Closed before Written Feedback		0	0		
Written Feedback Provided		44	18		
Written Feedback Provided Within 40 Days		44	18		
Written Feedback Pending		0	7		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		100.00%	100.00%		

TAP Pilot Enrollment Data  
Table 13.4 - TAP Pilot Enrollment Data

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	19	47	28		
Enrollment Requests Accepted	12	40	24		
Enrollment Requests Not Accepted	7	7	2		
Enrollment Requests Pending	0	0	2		



Section 13 TAP Documents - Office Level Metric

Table 13.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices  
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0		
Closed before Teleconference		0	0		
Teleconferences Held		0	0		
Teleconferences Held Within 14 Days		0	0		
Teleconferences Pending		0	0		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		N/A	N/A		

Table 13.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices  
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 21 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		N/A	N/A		

Table 13.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices  
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 40 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		N/A	N/A		

Table 13.4 - OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices  
TAP Pilot Enrollment Data

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	0	1		
Enrollment Requests Accepted	0	0	1		
Enrollment Requests Not Accepted	0	0	0		
Enrollment Requests Pending	0	0	0		

Table 13.1 OHT2 - Office of Cardiovascular Devices  
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		21	15		
Closed before Teleconference		0	0		
Teleconferences Held		21	14		
Teleconferences Held Within 14 Days		20	14		



Teleconferences Pending		0	1		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		95.24%	100.00%		

**Table 13.2 OHT2 - Office of Cardiovascular Devices**  
**TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal**

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		3	3		
Closed before Written Feedback		0	0		
Written Feedback Provided		3	3		
Written Feedback Provided Within 21 Days		3	2		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		100.00%	66.67%		

**Table 13.3 OHT2 - Office of Cardiovascular Devices**  
**TAP MDUFA V Written Feedback (Other) Performance Goal**

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		34	18		
Closed before Written Feedback		0	0		
Written Feedback Provided		34	13		
Written Feedback Provided Within 40 Days		34	13		
Written Feedback Pending		0	5		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		100.00%	100.00%		

**Table 13.4 - OHT2 - Office of Cardiovascular Devices**  
**TAP Pilot Enrollment Data**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	19	21	7		
Enrollment Requests Accepted	12	16	6		
Enrollment Requests Not Accepted	7	5	1		
Enrollment Requests Pending	0	0	0		

**Table 13.1 OHT3 - Office of Gastorenal, ObGyn, General Hospital, and Urology Devices**  
**TAP MDUFA V Teleconference Engagement Performance Goal**

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0		
Closed before Teleconference		0	0		
Teleconferences Held		0	0		
Teleconferences Held Within 14 Days		0	0		
Teleconferences Pending		0	0		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		N/A	N/A		

**Table 13.2 OHT3 - Office of Gastorenal, ObGyn, General Hospital, and Urology Devices**  
**TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal**

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		



Written Feedback Provided		0	0		
Written Feedback Provided Within 21 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		N/A	N/A		

**Table 13.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**TAP MDUFA V Written Feedback (Other) Performance Goal**

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 40 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		N/A	N/A		

**Table 13.4 - OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices**  
**TAP Pilot Enrollment Data**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	1	1		
Enrollment Requests Accepted	0	0	0		
Enrollment Requests Not Accepted	0	1	1		
Enrollment Requests Pending	0	0	0		

**Table 13.1 OHT4 - Office of Surgical and Infection Control Devices**  
**TAP MDUFA V Teleconference Engagement Performance Goal**

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0		
Closed before Teleconference		0	0		
Teleconferences Held		0	0		
Teleconferences Held Within 14 Days		0	0		
Teleconferences Pending		0	0		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		N/A	N/A		

**Table 13.2 OHT4 - Office of Surgical and Infection Control Devices**  
**TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal**

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 21 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		N/A	N/A		

**Table 13.3 OHT4 - Office of Surgical and Infection Control Devices**  
**TAP MDUFA V Written Feedback (Other) Performance Goal**

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
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Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 40 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		N/A	N/A		

**Table 13.4 - OHT4 - Office of Surgical and Infection Control Devices  
TAP Pilot Enrollment Data**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	0	0		
Enrollment Requests Accepted	0	0	0		
Enrollment Requests Not Accepted	0	0	0		
Enrollment Requests Pending	0	0	0		

**Table 13.1 OHT5 - Office of Neurological and Physical Medicine Devices  
TAP MDUFA V Teleconference Engagement Performance Goal**

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		10	14		
Closed before Teleconference		0	0		
Teleconferences Held		10	11		
Teleconferences Held Within 14 Days		10	10		
Teleconferences Pending		0	3		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		100.00%	90.91%		

**Table 13.2 OHT5 - Office of Neurological and Physical Medicine Devices  
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal**

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	3		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	3		
Written Feedback Provided Within 21 Days		0	3		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		N/A	100.00%		

**Table 13.3 OHT5 - Office of Neurological and Physical Medicine Devices  
TAP MDUFA V Written Feedback (Other) Performance Goal**

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		10	7		
Closed before Written Feedback		0	0		
Written Feedback Provided		10	5		
Written Feedback Provided Within 40 Days		10	5		
Written Feedback Pending		0	2		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		100.00%	100.00%		

**Table 13.4 - OHT5 - Office of Neurological and Physical Medicine Devices  
TAP Pilot Enrollment Data**



Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	25	8		
Enrollment Requests Accepted	0	24	8		
Enrollment Requests Not Accepted	0	1	0		
Enrollment Requests Pending	0	0	0		

**Table 13.1 OHT6 - Office of Orthopedic Devices**  
**TAP MDUFA V Teleconference Engagement Performance Goal**

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0		
Closed before Teleconference		0	0		
Teleconferences Held		0	0		
Teleconferences Held Within 14 Days		0	0		
Teleconferences Pending		0	0		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		N/A	N/A		

**Table 13.2 OHT6 - Office of Orthopedic Devices**  
**TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal**

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 21 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		N/A	N/A		

**Table 13.3 OHT6 - Office of Orthopedic Devices**  
**TAP MDUFA V Written Feedback (Other) Performance Goal**

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 40 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		N/A	N/A		

**Table 13.4 - OHT6 - Office of Orthopedic Devices**  
**TAP Pilot Enrollment Data**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	0	5		
Enrollment Requests Accepted	0	0	5		
Enrollment Requests Not Accepted	0	0	0		
Enrollment Requests Pending	0	0	0		

**Table 13.1 OHT7 - Office of In Vitro Diagnostics**  
**TAP MDUFA V Teleconference Engagement Performance Goal**



Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0		
Closed before Teleconference		0	0		
Teleconferences Held		0	0		
Teleconferences Held Within 14 Days		0	0		
Teleconferences Pending		0	0		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		N/A	N/A		

**Table 13.2 OHT7 - Office of In Vitro Diagnostics**  
**TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal**

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 21 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		N/A	N/A		

**Table 13.3 OHT7 - Office of In Vitro Diagnostics**  
**TAP MDUFA V Written Feedback (Other) Performance Goal**

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 40 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		N/A	N/A		

**Table 13.4 - OHT7 - Office of In Vitro Diagnostics**  
**TAP Pilot Enrollment Data**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	0	0		
Enrollment Requests Accepted	0	0	0		
Enrollment Requests Not Accepted	0	0	0		
Enrollment Requests Pending	0	0	0		

**Table 13.1 OHT8 - Office of Radiological Health**  
**TAP MDUFA V Teleconference Engagement Performance Goal**

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0		
Closed before Teleconference		0	0		
Teleconferences Held		0	0		
Teleconferences Held Within 14 Days		0	0		
Teleconferences Pending		0	0		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		N/A	N/A		



Table 13.2 OHT8 - Office of Radiological Health  
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 21 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		N/A	N/A		

Table 13.3 OHT8 - Office of Radiological Health  
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 40 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		N/A	N/A		

Table 13.4 - OHT8 - Office of Radiological Health  
TAP Pilot Enrollment Data

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received	0	0	6		
Enrollment Requests Accepted	0	0	4		
Enrollment Requests Not Accepted	0	0	0		
Enrollment Requests Pending	0	0	2		



## Appendix A      Variable Definitions

### Section 1      PMA Originals and Panel Track Supplements

**Table 1.1 and Tables 1.1.x      PMA Original and Panel Track Supplements – Acceptance Review Decision - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year.
2	Number Closed Before First RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted First RTA review	Number Received (line 1) that got “RTA Accepted” (RTAA) decision in the first RTA review cycle entered by reviewer.
4	Number Without a First Cycle RTA Review and > 15 Days Since Date Received	Number Received (line 1) that got “Did not perform RTA” (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved.
5	Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted for Filing Review on First Cycle	Number of submissions received in this fiscal year (line 1) that got a “Refuse to accept” (RTA1) decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Filing Review on First Cycle	Number Not Accepted for Filing Review (line 6) divided by the total of Number Accepted (line 3), Number without RTA Review and > 15 Days since Date Received (line 4), and Number Not Accepted for Filing Review (line 6).



**Table 1.2 and Tables 1.2.x****PMA Originals and Panel Track Supplements – Filing Review  
Decision - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year.
2	Number Accepted	Number Received (line 1) that got “RTA Accepted” (RTAA) or RTAN decision in the first RTA review cycle entered by reviewer.
3	Completed RTF	Number of submissions with the first RTF review completed in this fiscal year.
4	Number Not Filed	Number of submissions with completed RTF (line 3) that got the NOFI decision in the first RTF review.
5	Rate of Submissions Not Filed	Number Not Filed (line 4) divided by Number with completed RTF (line 3).



**Table 1.3 and Tables 1.3.x****PMA Originals and Panel Track Supplements Substantive Interaction Performance Goal - Definitions**

#	Measure	Description
1	Eligible for SI	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	SI Goal Met	Number of submissions with SI action within goal.
3	SI Goal Not Met	Number of submissions with SI action taken past goal.
4	SI Pending Within Goal	Number of submissions that are under review with no SI within goal.
5	SI Pending Past Goal	Number of submissions that are under review with no SI past goal.
6	Closed Without SI	Number of submissions that are closed with a MDUFA or final decision that does not qualify as SI and that did not have an SI prior to that decision (i.e., converted and withdrawn).
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).



**Table 1.4 and Tables 1.4.x****PMA Originals and Panel Track Supplements Substantive Interaction Metric – Time to Substantive Interaction - Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of PMA Originals and Panel Track Supplements filed in this fiscal year that had an SI.
2	Average Number of FDA Days to Substantive Interaction	Average number of FDA days across all PMA Originals and Panel Track Supplements with SI (line 1).
3	20 <sup>th</sup> Percentile FDA Days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA Days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA Days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA Days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA Days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).



**Tables 1.5 and Tables 1.5.x****PMA Originals and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal - Definitions**

#	Measure	Description
1	Number of PMAs Filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and did not have Panel review requested.
2	Non-MDUFA Decisions	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decisions	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decisions Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).



**Table 1.6 and Tables 1.6.x****PMA Originals and Panel Track Supplements (With Panel Review)  
MDUFA V Decision Performance Goal - Definitions**

#	Measure	Description
1	Number of PMAs Filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and had a Panel review requested.
2	Non-MDUFA Decisions	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decisions	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decisions Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

**Table 1.7 and Tables 1.7.x****PMA Originals and Panel Track Supplements (Without Panel Review) Performance Metric – Time to MDUFA V Decision - Definitions**

#	Measure	Description
1	Number With MDUFA Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, did not have Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.



**Table 1.8 and Tables 1.8.x****PMA Originals and Panel Track Supplements (With Panel Review)  
Performance Metric – Time to MDUFA V Decision - Definitions**

#	Measure	Description
1	Number With MDUFA Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, had Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 1.9 and Tables 1.9.x****PMA Originals and Panel Track Supplements (Without Panel Review) MDUFA V Performance Metric – Rates of Withdrawal, Not Approvable and Deleted - Definitions**

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and did not have Panel Review requested.
2	Number With MDUFA decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawal	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Number of Deleted	Number of submissions filed (line 1) with MDUFA decision of DELE (Deleted).
6	Rate of Withdrawal	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
7	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line 2).



**Table 1.10 and Tables 1.10.x PMA Originals and Panel Track Supplements (With Panel Review)  
Performance Metric – Rate of Withdrawal, Not Approvable and Deleted - Definitions**

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and had Panel Review requested.
2	Number With MDUFA Decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawal	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Number of Deleted	Number of submissions filed (line 1) with MDUFA decision of DELE (Deleted).
6	Rate of Withdrawal	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
7	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line 2).



**Table 1.11 and Tables 1.11.x PMA Originals and Panel Track Supplements (Without Panel Review) Performance Metric – Submissions Missing Performance Goal - Definitions**

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, without Panel Review, with number of FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA Days for Submissions that Missed the Goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed the Goal	Mean industry days for submissions that missed the goal (line 1).

**Table 1.12 and Tables 1.12.x PMA Originals and Panel Track Supplements (With Panel Review) Performance Metric – Submissions Missing Performance Goal - Definitions**

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, with Panel Review, with number FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA Days for Submissions that Missed the Goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed the Goal	Mean industry days for submissions that missed the goal (line 1).



**Tables 1.13 and Tables 1.13.x LDT PMA Originals and Panel-Track Supplements MDUFA V Metric\***  
**- Definitions**

#	Measure	Description
1	Number of PMAs Filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	Non-MDUFA Decision	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decision	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decision Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

\*Includes submissions that went to panel



**Tables 1.14 and Tables 1.14.x Conventional IVD (Non-LDT) PMA Originals & Panel-Track Supplements MDUFA V Metric\* - Definitions**

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	Non-MDUFA Decisions	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decisions	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decisions Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

\*Includes submissions that went to panel



## Section 2 PMA 180 Day Supplements

**Table 2.1 and Tables 2.1.x PMA 180 Day Supplements Substantive Interaction Goal – Definitions**

#	Measure	Description
1	Eligible for SI	Number of 180 day PMA supplements received in this fiscal year.
2	SI Goal Met	Number of submissions with an SI action taken within goal.
3	SI Goal Not Met	Number of submissions with an SI action taken past goal.
4	SI Pending Within Goal	Submissions that are under review within goal.
5	SI Pending Past Goal	Submissions that are under review past goal.
6	Closed Without SI	Number of submissions that are closed with a MDUFA (other than APPR) or NON-MDUFA decision but without an SI
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

**Table 2.2 and Tables 2.2.x PMA 180 Day Supplements MDUFA V Decision Performance Goal – Definitions**

#	Measure	Description
1	Supplements Received	Number of 180 day PMA supplements received in this fiscal year.
2	Non-MDUFA Decision	Supplements received (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMa).
3	MDUFA Decision	Supplements received (line 1) and closed with a MDUFA decision.
4	MDUFA Decision Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	Supplements Pending MDUFA Decision	Number of supplements received (line 1) that do not have a MDUFA decision or a final decision.
6	Supplements Pending MDUFA Decision Past Goal	Number of supplements pending MDUFA Decision (line 5) past goal. These supplements already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA Decisions made on time (line 4) divided by the total number of supplements with MDUFA Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).



**Table 2.3 and Tables 2.3.x****PMA 180 Day Supplements MDUFA V Performance Metric – Rate of Not Approvable – Definitions**

#	Measure	Description
1	Number Received	Number of PMA 180 Day Supplements received in this fiscal year.
2	Number With MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line2).

**Table 2.4 and Tables 2.4.x****PMA 180 Day Supplements MDUFA V Performance Metric – Submissions Missing Performance Goal – Definitions**

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of 180 Day supplements, received in this fiscal year, with number FDA days to MDUFA V decision exceeding number of goal days.
2	Mean FDA Days for Submissions that Missed Goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed Goal	Mean industry days for supplements that missed the goal (line 1).



### Section 3 PMA Real Time Supplements

**Table 3.1 and Tables 3.1.x PMA Real Time Supplements MDUFA V Decision Performance Goal – Definitions**

#	Measure	Description
1	Supplements Received	Number of Real Time PMA supplements that were received in this fiscal year.
2	Non-MDUFA Decision	Supplements received in this fiscal year (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMa).
3	MDUFA Decision	Supplements received in this fiscal year (line 1) and closed with a MDUFA decision.
4	MDUFA Decision Goal Met	Submissions with MDUFA decisions (line 3) within goal.
5	Supplements Pending MDUFA Decision	Number of supplements received in this fiscal year (line 1) that do not have a MDUFA decision and are not closed with a final decision.
6	Supplements Pending MDUFA Decision Past Goal	Number of supplements pending MDUFA Decision (line 5) past goal. These supplements already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA Decisions made on time (line 4) divided by the total number of supplements with MDUFA Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

**Table 3.2 and Tables 3.2.x PMA Real Time Supplements MDUFA V Performance Metric – Rate of Not Approvable – Definitions**

#	Measure	Description
1	Number Received	Number of PMA Real Time Supplements received in this fiscal year.
2	Number With MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line 2).



**Table 3.3 and Tables 3.3.x****PMA Real Time PMA Supplements MDUFA V Performance Metric –  
Submissions Missing Performance Goal – Definitions**

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of Real Time Supplements, received in this fiscal year, that also have a MDUFA decision, with number of FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA Days for Submissions that Missed Goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed Goal	Mean industry days for supplements that missed the goal (line 1).



## Section 5 PMA Annual Metrics and Goals

**Table 5.1 PMAs (All Review Tracks) Annual General Metrics – Definitions**

#	Measure	Description
1	Premarket Report Submissions	Number of PMA Original submissions, with Reprocessed flag set to “Yes”, received in this fiscal year.
2	Original PMAs (Panel) – Breakthrough	Number of PMA Original submissions with Panel review requested and Breakthrough flag set to “Yes”, received in this fiscal year.
3	Original PMAs (No Panel) – Breakthrough	Number of PMA Original submissions with no Panel review requested and Breakthrough flag set to “Yes”, received in this fiscal year.
4	Original PMAs (Panel) – Non- Breakthrough	Number of PMA Original submissions with Panel review requested and Breakthrough flag set to “No” or not set (blank), received in this fiscal year.
5	Original PMAs (No Panel) – Non-Breakthrough	Number of PMA Original submissions with no Panel review requested and Breakthrough flag set to “No” or not set (blank), received in this fiscal year.
6	Panel Track Supplements (Panel) – Breakthrough	Number of PMA Panel Track Supplements with Panel review requested and Breakthrough flag set to “Yes”, received in this fiscal year.
7	Panel Track Supplements (No Panel) – Breakthrough	Number of PMA Panel Track Supplements with no Panel review requested and Breakthrough flag set to “Yes”, received in this fiscal year.
8	Panel Track Supplements (Panel) – Non-Breakthrough	Number of PMA Panel Track Supplements with Panel review requested and Breakthrough flag set to “No” or not set (blank), received in this fiscal year.
9	Panel Track Supplements (No Panel) – Non-Breakthrough	Number of PMA Panel Track Supplements with no Panel review requested and Breakthrough flag set to “No” or not set (blank), received in this fiscal year.
10	PMA Modules	Number of PMA Modules received with a valid eCopy or taken off eCopy hold in this fiscal year.
11	180-Day Supplements	Number of PMA 180-Day supplements received in this fiscal year.
12	Real-Time Supplements	Number of PMA Real-Time supplements received in this fiscal year.



**Table 5.2**      **PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Definitions**

#	Measure	Description
1	Number Filed	Total number of PMA Original and Panel Track Supplement submissions filed in this fiscal year.
2	Number With a Decision (MDUFA or Non-MDUFA)	Number of submissions filed in this fiscal year (line 1) that were closed with either MUDFA or non-MDUFA decision.
3	% of FY Closed	Number with a decision (line 2) divided by Number Filed (line 1).

**Table 5.3**      **PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Three-Year Rolling Average Time to MDUFA Decision – Definitions**

#	Measure	Description
1	Number With a MDUFA Decision	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision.
2	Number With a MDUFA Decision After Trimming the Upper and Lower 5%	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision (line 1) excluding 5% of submissions with the lowest number of Total Days to MDUFA V decision and 5% of submissions with the highest number of Total Days to MDUFA V decision.
3	Three-Year Rolling Average Total Time to MDUFA Decision	Average Total Time (FDA and Industry) for the three-year receipt cohort. Each of the three years has to be closed (95% of submissions must have a MDUFA decision) in order for this value to be calculated. If any of these three years is not closed, then this cell shall be left blank. The rolling average shall be calculated for submissions with MDUFA decision, excluding outliers (top and bottom 5%) – these submissions are counted on line 2. For FY 2011 and FY 2012 Total Time to MDUFA II (two) decision will be used.



## Section 6    510(k) MDUFA V Performance    (Quarterly Data Exclude Third Party Review)

**Table 6.1 and Tables 6.1.x    510(k) Acceptance Review Decision – Definitions**

#	Measure	Description
1	Number Received	Number of 510(k) submissions received in this fiscal year.
2	Closed Before First RTA or TS Action	Number Received (line 1) that were closed with a final decision before RTA or Technical Screening action.
3	Number Accepted or Passed TS on First Cycle	Number Received (line 1) that received an “RTA Accepted” (RTAA) decision or passed Technical Screening (TSOK) in the first RTA/TS review cycle.
4	Number Without a RTA or TS Review and > 15 Days Since Date Received	Number Received (line 1) that did not receive an RTA or TS decision in the 1 <sup>st</sup> 15 days of the first RTA/TS review cycle. Decision codes are RTAN, RTAS, RTAW and TSRN) decision in the first RTA review cycle. An RTAN/TSRN decision is automatically recorded by CTS at the end of day 15 of RTA/TS review, if no other RTA/TS decision is made. This RTA/TS decision means that the 510(k) is deemed accepted/deemed to have passed Technical Screening. The data contained in this row should be combined with the data in the row above, “Number Accepted or Passed TS on First Cycle”, to determine the total number of submissions accepted or passed on the first RTA or TS
5	Number Without a RTA or TS Review and <= 15 Days Since Date Received	Number Received (line 1) that are still in the first RTA /TS review cycle and have not yet reached the 15 <sup>th</sup> day of that cycle.
6	Number Not Accepted or Failed TS on First Cycle	Number of submissions received in this fiscal year (line 1) that got a “Not Accepted” (RTA1/TSIC) decision in the first RTA/TS review cycle.
7	Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	Number Not Accepted or Failed TS on First Cycle (line 6) expressed as a percentage of the sum of the Number Accepted or Passed TS on First Cycle (line 3), Number Without a RTA or TS Review and <= 15 Days Since Date Received (line 4), and Number Not Accepted or Failed TS on First Cycle (line 6).



**Table 6.2 and Tables 6.2.x 510(k) Substantive Interaction Performance Goal – Definitions**

#	Measure	Description
1	Eligible for SI	Number of 510(k) submissions accepted or passed via the RTA/TS process as of quarter end date (RTAA, RTAN, RTAW, RTAS, TSOK, TSRN). For brevity, we refer to this as "accepted" in subsequent 510k definitions.
2	Deleted or Withdrawn Prior to SI	Number of 510(k)s that were Eligible for SI (line 1) but with the following Non-MDUFA decisions made as of the quarter end date and before any SI action: WTDR, DELE.
3	SI Within 60 FDA days	Number of submissions with SI action within 60 FDA days.
4	SI Over 60 FDA days	Number of submissions with SI action taken in more than 60 FDA days.
5	SI Pending within 60 FDA days	Submissions that are awaiting SI and where 60 days have not yet elapsed.
6	SI Pending over 60 FDA days	Submissions that are awaiting SI and where 60 days have elapsed.
7	510(k)s NSE Without SI	Number of 510(k) submissions that are closed with an NSE decision and did not have an SI.
8	Current SI Performance Percent within 60 FDA days	Number of submissions with SI within 60 FDA days (line 3) expressed as a percentage of the sum of the number of submissions that received an SI (line 3 and line 4), the number of submissions that missed the SI goal or are awaiting SI after 60 days as of quarter end (line 6), and the number of submissions that were found NSE without receiving an SI (line 7).



**Table 6.3 and Tables 6.3.x****510(k) Substantive Interaction Metric – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interaction	Number of 510(k) submissions RTA accepted or passed TS in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to substantive interaction across all 510(k) submissions with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).



**Tables 6.4 and Tables 6.4.x 510(k) MDUFA V Decision Performance Goal– Definitions**

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions accepted in this fiscal year.
2	Non-MDUFA Decision	Number of submissions accepted (line 1) and closed with a non-MDUFA decision (not SE or NSE).
3	MDUFA Decision (SE/NSE)	Number of submissions accepted (line 1) and closed with a MDUFA decision (SE or NSE).
4	MDUFA Decision within 90 FDA Days	Number of submissions with MDUFA decision (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA Decision Over 90 FDA Days	Number of submissions pending MDUFA Decision (line 5) for more than 90 FDA Days. These submissions have missed the MDUFA review goal.
7	Current Performance Percent Within 90 FDA Days	Number of submissions with MDUFA Decisions within 90 FDA Days (line 4) expressed as a percentage of the sum of the number of submissions with MDUFA Decisions (line 3) and pending submissions that have missed the MDUFA goal (line 6).

**Table 6.5 and Tables 6.5.x 510(k) Time to MDUFA V Decision– Definitions**

#	Measure	Description
1	Average Review Cycles	Average number of review cycles (after submission is accepted for review) for 510(k)s with a MDUFA decision (line 2).
2	Number with MDUFA Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days to MDUFA V decision.



**Table 6.6 and Tables 6.6.x****510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision– Definitions**

#	Measure	Description
1	510(k) Accepted	Number of 510(k) submissions accepted in this fiscal year.
2	Number with MDUFA Decision	Number submissions accepted (line 1) that had a MDUFA decision.
3	Number of SE Decision	Number of submissions accepted (line 1) that had an SE MDUFA decision.
4	Number of NSE Decision	Number of submissions accepted (line 1) that had an NSE MDUFA decision.
5	Number of Withdrawal	Number of submissions accepted (line 1) and closed with Withdrawal final decision.
6	Number Deleted	Number of submissions accepted (line 1) and closed with Delete final decision.
7	Rate of SE Decision	Number of SE decisions (line 3) expressed as a percentage of the Number with MDUFA decision (line 2).
8	Rate of NSE Decision	Number of NSE decisions (line 4) expressed as a percentage of the Number with MDUFA decision (line 2).
9	Rate of Withdrawal	Number of Withdrawals (line 5) expressed as a percentage of the Number Accepted (line 1).
10	Rate of Deleted	Number of Deleted (line 6) expressed as a percentage of the by Number Accepted (line 1).

**Table 6.7 and Tables 6.7.x****510(k) Performance Metric – Submissions Missing Performance Goal – Definitions**

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of 510(k) submissions accepted in this fiscal year that had a MDUFA decision with more than 90 FDA days.
2	Mean FDA Days for Submissions that Missed the Goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).



**Tables 6.8 and Tables 6.8.x LDT 510(k) MDUFA V Decision Metric– Definitions**

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions for LDTs accepted in this fiscal year.
2	Non-MDUFA Decision	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA decision (not SE or NSE).
3	MDUFA Decision (SE/NSE)	Number of LDT submissions accepted (line 1) and closed with a MDUFA decision (SE or NSE).
4	MDUFA Decision within 90 FDA Days	Number of LDT submissions with MDUFA decision (line 3) made within 90 FDA days.
5	510(k)s pending MDUFA Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) pending MDUFA Decision over 90 FDA days	Number of LDT submissions pending MDUFA Decision (line 5) for more than 90 FDA Days. These submissions already missed the MDUFA V review goal.
7	Current Performance Percent within 90 FDA Days	Number of LDT submissions with MDUFA decision within 90 FDA Days (line 4) divided by the total number of LDT submissions with MDUFA Decision (line 3) and pending LDT submissions that already missed the MDUFA goal (line 6).



**Tables 6.9 and Tables 6.9.x Conventional IVD (Non-LDT) 510(k) MDUFA V Decision Metric–Definitions**

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions for non-LDT IVDs accepted in this fiscal year.
2	Non-MDUFA Decision	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA decision (not SE or NSE).
3	MDUFA Decision (SE/NSE)	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA V decision (SE or NSE).
4	MDUFA Decision within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA decisions (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA Decision Over 90 FDA Days	Number of non-LDT IVD submissions pending MDUFA Decision (line 5) for more than 90 FDA Days. These submissions already missed the MDUFA V review goal.
7	Current Performance Percent within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA Decision within 90 FDA Days (line 4) divided by the total number of non-LDT IVD submissions with MDUFA Decision (line 3) and pending non-LDT IVD submissions that already missed the MDUFA goal (line 6).



## Section 7    510(k) Annual General Metrics (Annual data includes Third Party reviews)

**Table 7.1            CDRH - 510(k) Annual General Metrics – 510(k)s Received by Type – Definitions**

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. This metric includes Third Party 510(k) submissions.
2	Number of Traditional submissions	Number of Traditional Non-Third Party 510(k) submissions accepted in this fiscal year.
3	Number of Special submissions	Number of Special Non-Third Party 510(k) submissions accepted in this fiscal year.
4	Number of Abbreviated submissions	Number of Abbreviated Non-Third Party 510(k) submissions accepted in this fiscal year.
5	Average number of days to Accept / Refuse to Accept	Average number of days in the first RTA/TS review cycle for Non-Third Party 510(k) submissions.
6	Number of Third Party submissions	Number of Third Party 510(k) submissions received in this fiscal year.



**Table 7.2 CDRH - 510(k) Annual Shared Outcome Goal – Definitions**

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. This metric includes Third Party 510(k) submissions.
2	Currently Under Review	Number of 510(k) submissions accepted (line 1) that are still under review (no final decision yet).
3	Number with Non-MDUFA decision	Number of 510(k) submissions accepted (line 1) that were closed with a Non-MDUFA decision.
4	Number with MDUFA Decision	Number of 510(k) submissions accepted (line 1) that had a MDUFA decision.
5	Percent of cohort closed	Number with MDUFA decision (line 4) expressed as a percentage of the sum of Currently Under Review (line 2) and Number with MDUFA Decision (line 4).
6	Number with MDUFA decision after trimming the upper and lower 2%	Number of 510(k) submissions with MDUFA Decision (line 4) excluding the 2% of submissions with the lowest number of Total Days to MDUFA V decision and the 2% of submissions with the highest number of Total Days to MDUFA decision.
7	Average Total Time to MDUFA decision	Average Total Time (FDA and Industry) to MDUFA decision, where the denominator is the trimmed number with MDUFA decision (line 6). If the cohort has not yet reached 99% closure, "N/A" shall be displayed instead.

**Table 7.3 CDRH - 510(k) Third Party Performance – Definitions**

#	Measure	Description
1	Number of Third Party Submissions	Number of Third Party 510(k) submissions received in this fiscal year.
2	90 <sup>th</sup> Percentile FDA Days to MDUFA Decision	The 90 <sup>th</sup> percentile of FDA days to MDUFA decision on 3 <sup>rd</sup> Party 510(k) submissions received in this fiscal year



## Section 8 De Novo MDUFA V Performance

**Table 8.1 and Tables 8.1.x De Novo Acceptance Review Decision - Definitions**

#	Measure	Description
1	Number Received	Number of De Novo submissions received in this fiscal year.
2	Closed Before First RTA or TS Action	Number Received (line 1) that were closed with a final decision before RTA or Technical Screening action.
3	Number Accepted or Passed TS on First Cycle	Number Received (line 1) that received an "RTA Accepted" (RTAA) decision or passed Technical Screening (TSOK) in the first RTA/TS review cycle.
4	Number Without a RTA or TS Review and > 15 Days Since Date Received	Number Received (line 1) that did not receive an RTA or TS decision in the 1 <sup>st</sup> 15 days of the first RTA/TS review cycle. Decision codes are RTAN, RTAS, RTAW and TSRN) decision in the first RTA review cycle. An RTAN/TSRN decision is automatically recorded by CTS at the end of day 15 of RTA/TS review, if no other RTA/TS decision is made. This RTA/TS decision means that the 510(k) is deemed accepted/deemed to have passed Technical Screening. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 5 in flowchart).
5	Number Without a RTA or TS Review and <= 15 Days Since Date Received	Number Received (line 1) that are still in the first RTA /TS review cycle and have not yet reached the 15 <sup>th</sup> day of that cycle.
6	Number Not Accepted or Failed TS on First Cycle	Number of submissions received in this fiscal year (line 1) that got a "Not Accepted" (RTA1/TSIC) decision in the first RTA/TS review cycle.
7	Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	Number Not Accepted or Failed TS on First Cycle (line 6) expressed as a percentage of the sum of the Number Accepted or Passed TS on First Cycle (line 3), Number Without a RTA or TS Review and <= 15 Days Since Date Received (line 4), and Number Not Accepted or Failed TS on First Cycle (line 6).



**Tables 8.2 and Tables 8.2.x De Novo MDUFA V Decision Performance Goal– Definitions**

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions accepted or passed via the RTA/TS process as of quarter end date (RTAA, RTAN, RTAW, RTAS, TSOK, TSRN). For brevity, we refer to this as "accepted" in subsequent De Novo definitions.
2	Non-MDUFA Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA Decisions	Number of submissions accepted (line 1) and closed with a MDUFA decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA Decisions within 150 FDA Days	Number of submissions with MDUFA decisions (line 3) made within 150 FDA days.
5	De Novos pending MDUFA V Decision	Number of submissions accepted (line 1) and still under review.
6	De Novos pending MDUFA V Decision over 150 FDA days	Number of submissions pending MDUFA Decision (line 5) for more than 150 FDA Days. These submissions have missed the MDUFA review goal.
7	Current Performance Percent within 150 FDA Days	Number of submissions with MDUFA Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already have missed the MDUFA goal (line 6).

**Table 8.3 and Tables 8.3.x De Novo Time to MDUFA V Decision – Definitions**

#	Measure	Description
1	Average Review Cycles	Average number of review cycles (after submission is accepted for review) for De Novos with a MDUFA decision (line 2).
2	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days to MDUFA decision.



**Table 8.4 and Tables 8.4.x****De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete Decision – Definitions**

#	Measure	Description
1	De Novos Accepted	Number of De Novos submissions accepted in this fiscal year.
2	Number with MDUFA V Decisions	Number submissions accepted (line 1) that had a MDUFA decision.
3	Number with Granted Decisions	Number of submissions accepted (line 1) that had a Granted MDUFA decision.
4	Number with Declined Decisions	Number of submissions accepted (line 1) that had a Declined MDUFA decision.
5	Number of Withdrawals	Number of submissions accepted (line 1) that had a Withdrawn MDUFA decision.
6	Number of Deleted	Number of submissions accepted (line 1) and closed that had a Deleted MDUFA decision
7	Rate of Granted Decisions	Number of Granted decisions (line 3) divided by Number with MDUFA decision (line 2).
8	Rate of Declined Decisions	Number of Declined decisions (line 4) divided by Number with MDUFA decision (line 2).
9	Rate of Withdrawals	Number of Withdrawals (line 5) divided by Number with MDUFA decision (line 2).
10	Rate of Deleted	Number of Deleted (line 6) divided by Number with MDUFA decision (line 2).

**Table 8.5 and Tables 8.5.x****De Novo Performance Metrics – Submissions Missing Performance Goals – Definitions**

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of submissions with MDUFA decision made beyond 150 FDA days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed the Goal	Mean industry days for submissions that missed the goal (line 1).



**Tables 8.6 and Tables 8.6.x LDT De Novo MDUFA V Decision Metrics – Definitions**

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions for LDTs accepted in this fiscal year.
2	Non-MDUFA V Decisions	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA V Decisions	Number of LDT submissions accepted (line 1) and closed with a MDUFA decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA V Decisions Within 150 FDA Days	Number of LDT submissions with MDUFA decisions (line 3) made within 150 FDA days.
5	De Novos Pending MDUFA V Decision	Number of LDT submissions accepted (line 1) and still under review.
6	De Novos Pending MDUFA V Decision over 150 FDA days	Number of LDT submissions pending MDUFA Decision (line 5) for more than 150 FDA Days. These submissions have missed the MDUFA V review goal.
7	Current Performance Percent within 150 FDA Days	Number of LDT submissions with MDUFA Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of LDT submissions with MDUFA Decisions (line 3) and pending LDT submissions that have missed the MDUFA goal (line 6).



**Tables 8.7 and Tables 8.7.x****Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics – Definitions**

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions for non-LDT IVDs accepted in this fiscal year.
2	Non-MDUFA Decisions	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA Decisions	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA Decisions within 150 FDA Days	Number of non-LDT IVD submissions with MDUFA decisions (line 3) made within 150 FDA days.
5	De Novos Pending MDUFA Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	De Novos Pending MDUFA Decision Over 150 FDA Days	Number of non-LDT IVD submissions pending MDUFA Decision (line 5) for more than 150 FDA Days. These submissions have missed the MDUFA review goal.
7	Current Performance Percent Within 150 FDA Days	Number of non-LDT IVD submissions with MDUFA Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of non-LDT IVD submissions with MDUFA Decisions (line 3) and pending non-LDT IVD submissions that have missed the MDUFA goal (line 6).

**Section 8 Annual Metrics for De Novo Requests****Table 8.8 CDRH – Annual General Metric Report for De Novo Requests - Definitions**

#	Measure	Description
1	Number Accepted	Number of De Novo submissions accepted in this fiscal year as of the report cutoff date.
4	Average Number of Days to Accept/Refuse to Accept/Technical Screening	Average number of days in the first RTA/TS review cycle



## Section 9 Pre-Submissions

**Table 9.1 and Tables 9.1.x Pre-Sub Acceptance Review Decision – Definitions**

#	Measure	Description
1	Number Received	Number of Pre-Subs received in this fiscal year (includes Q-Sub types tracked as Pre-Sub Meeting, Pre-Sub Written Feedback, Breakthrough Interaction, and STeP Interaction).
2	Interactions for Breakthrough Designated Products & Products Included in STeP	Number of Breakthrough Interactions and STeP Interactions received in this fiscal year (excludes submissions tracked as Pre-Sub Meeting and Pre-Sub Written Feedback).
3	Number Closed Before RTA Action	Number Received (line 1) that were closed with a final decision before RTA action.
4	Number Accepted First RTA Cycle	Number Received (line 1) that had “RTA Accepted” (RTAA) decision in the first RTA review cycle entered by reviewer and submissions considered accepted upon receipt
5	Number Without First Cycle RTA Review and > 15 Days Since Date Received	Number Received (line 1) that had a “Did not perform RTA” (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. The data contained in this row should be combined with the data in the row above, “Number Accepted First RTA Cycle” to determine the total number of submissions accepted on the first RTA cycle.
6	Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	Number Received (line 1) that are still in the first RTA review cycle at the quarter end date.
7	Number Not Accepted First RTA Cycle	Number of submissions received in this fiscal year (line 1) that had a “Refuse to accept” (RTA1) decision in the first RTA review cycle.
8	Rate of Submissions Not Accepted for Review on First RTA Cycle	Number Not Accepted First RTA Cycle (line 7) expressed as a percentage of the sum of the Number Accepted First RTA Cycle (line 4), Number Without First Cycle RTA Review and > 15 Days Since Date Received (line 5), and Number Not Accepted First RTA Cycle (line 7).



**Table 9.2 and Tables 9.2.x MDUFA V Pre-Sub Performance Goals – Definitions**

#	Measure	Description
1	Number Accepted / Eligible for MDUFA Action	Number of submissions that passed via the RTA process as of quarter end date and Breakthrough/STeP Interactions
2	Number with Non-MDUFA Action	Number of submissions accepted (line 1) and closed with a non-MDUFA action (WTDR, JPND, JTRX, CLLR). Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.
3	Number with MDUFA Action	Number of submissions accepted (line 1) with a MDUFA action (EMAL, EMFB).
4	Written Feedback Provided Within Goal	Number of submissions with a MDUFA action (line 3) made by the MDUFA review goal (day 70 or 5 days prior to the meeting, whichever is sooner).
5	Number Pending MDUFA Action	Number of submissions accepted (line 1) still under review and pending feedback.
6	Pending MDUFA Action Past Goal	Number of submissions pending a MDUFA action (line 5) that have already missed the MDUFA review goal.
7	Number in MDUFA Cohort (up to max 4300)	<p>Number of submissions accepted with a MDUFA action (line 3) plus the number of submissions accepted and pending a MDUFA action (line 5).</p> <p>If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027.</p> <p>If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027.</p> <p>If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.</p>
8	Current Performance Percent Within Goal	Number of submissions with MDUFA actions made by the MDUFA review goal (line 4) expressed as a percentage of the sum of the number of submissions with a MDUFA action (line 3) and the number of submissions pending a MDUFA action and already passed the MDUFA review goal (line 6).



**Table 9.3 and Tables 9.3.x****MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort) – Definitions**

#	Measure	Description
1	Number with Written Feedback Sent	Number of Pre-Subs for which Written Feedback was sent to the sponsor by the reviewer entering a MDUFA V Decision of either "Email Reply" (EMAL) or "Email Feedback Sent Before Meeting" (EMFB). EMAL is used for Pre-Subs where there is no meeting requested. EMFB is used for Pre-Subs when a meeting is requested.
2	Average FDA Days to Written Feedback	Average number of days from the start of FDA review to MDUFA V Decision (EMAL or EMFB) for Pre-Subs with Written Feedback sent (line 1).
3	20 <sup>th</sup> Percentile FDA Days to Written Feedback	20 <sup>th</sup> percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
4	40 <sup>th</sup> Percentile FDA Days to Written Feedback	40 <sup>th</sup> percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
5	60 <sup>th</sup> Percentile FDA Days to Written Feedback	60 <sup>th</sup> percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
6	80 <sup>th</sup> Percentile FDA Days to Written Feedback	80 <sup>th</sup> percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
7	Maximum FDA Days to Written Feedback	Maximum FDA days (100 <sup>th</sup> percentile) to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).

**Table 9.4 and Tables 9.4.x****MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort) - Definitions**

#	Measure	Description
1	Meetings Not Scheduled by Day 30	Number of Pre-Subs for which a Meeting was Requested and a Meeting Date was not confirmed by the reviewer in CTS by day 30.
2	Average Days to Scheduling for Meetings Scheduled After Day 30	Average days to confirming a Meeting Date in CTS for Meetings not scheduled by Day 30 (line 1).



**Table 9.5 and Tables 9.5.x****MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort) - Definitions**

#	Measure	Description
1	Number of Meetings Required	Number of Pre-Sub Meeting Requests for which a Meeting was held and reviewer closed the submission in CTS by the quarter end date. Number of meetings requested and then held after written feedback is provided.
2	Meeting Minutes Submitted Within 15 Days of Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes were received within 15 days after Meeting Date.
3	Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes have not been received and it is still under 15 days since meeting (as of end of quarter).
4	Meeting Minutes Past 15 Days of Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes were received more than 15 days after Meeting Date.
5	Meeting Minutes Not Submitted and >15 Days Since Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes have not been received and more than 15 days have passed since the Meeting Date (as of end of quarter).
6	Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	Number of Meeting Minutes received within 15 days (line 2) divided by the total of Number of Meeting Minutes received within 15 days (line 2), Number of Meeting Minutes received past 15 days (line 4), and Number of Meeting Minutes which have not been received and >15 days since Meeting Date (line 5).

**Section 10 IDE Performance Metrics****Table 10.1 IDE Performance Metrics**

#	Measure	Description
1	Number of IDEs received	Number of IDEs received in the fiscal year.
2	Average number of cycles to approval or conditional approval of the IDE	The average number of cycles including the original submission and amendments that were submitted prior to the approval or conditional approval of an IDE.
3	Average number of amendments prior to approval or conditional approval of the IDE	The average number of amendments, to include only those amendments that were submitted to address deficiencies in the disapproval letter.



## Section 11 CLIA Waiver Annual Metrics

**Table 11.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions**

#	Measure	Description
1	Eligible for SI	Number of CLIA Waiver by Applications that were accepted in this fiscal year.
2	Withdrawn prior to SI	Number of submissions that were Withdrawn within 90 FDA days.
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days.
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days.
5	SI pending within 90 FDA days	Submissions that are awaiting SI and where 90 days have not yet elapsed.
6	SI pending over 90 FDA days	Submissions that have been under review over 90 FDA days and that do not have an SI.
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior.
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within goal (line 3) divided by the total number of submissions that either had an SI (line 3 and line 4) or did not have an SI but failed the SI goal (line 6 and line 7).



**Table 11.2 CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of CLIA Waiver by Applications accepted in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to SI across all CLIA Waivers with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).



**Table 11.3 CLIA Waiver (without Panel Review) MDUFA V Decision Performance Goals – Definitions**

#	Measure	Description
1	Eligible for MDUFA V Decisions	Number of CLIA Waiver by Applications that were accepted in this fiscal year, and did not have a panel review.
2	Non-MDUFA V Decisions	Number of submissions closed with a non-MDUFA V decision (not Approved, Denied, or Withdrawn).
3	MDUFA V Decisions	Number of submissions closed with a MDUFA V decision (Approved, Denied, or Withdrawn).
4	MDUFA V Decisions within 150 FDA Days	Number of submissions with MDUFA V decisions made within 150 FDA days.
5	CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	CLIA Waiver Applications pending MDUFA V Decision over 150 FDA days	Number of submissions pending MDUFA V Decision for more than 150 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 150 FDA Days	Number of submissions with MDUFA V Decisions within 150 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).



**Table 11.4 CLIA Waiver (with Panel Review) MDUFA V Decision Performance Goals) – Definitions**

#	Measure	Description
1	Eligible for MDUFA V Decisions	Number of CLIA Waiver by Applications that were accepted in this fiscal year, and had a panel review.
2	Non-MDUFA V Decisions	Number of submissions closed with a non-MDUFA V decision (not Approved, Denied, or Withdrawn).
3	MDUFA V Decisions	Number of submissions closed with a MDUFA V decision (Approved, Denied, or Withdrawn).
4	MDUFA V Decisions within 320 FDA Days	Number of submissions with MDUFA V decisions made within 320 FDA days.
5	CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	CLIA Waiver Applications pending MDUFA V Decision over 320 FDA days	Number of submissions pending MDUFA V Decision for more than 320 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 320 FDA Days	Number of submissions with MDUFA V Decisions within 320 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).

**Table 11.5 CLIA Waiver (without Panel Review) Time to MDUFA V Decision – Definitions**

#	Measure	Description
1	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision (Approved, Denied, or Withdrawn), and did not have a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 11.6 CLIA Waiver (with Panel Review) Time to MDUFA V Decision - Definitions**

#	Measure	Description
1	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision (Approved, Denied, or Withdrawn), and had a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.



## Section 12 Dual 510(k) and CLIA Waiver Annual Metrics

**Table 12.1 Dual 510(k) and CLIA Waiver Substantive Interaction Performance Goals – Definitions**

#	Measure	Description
1	Eligible for SI	Number of Dual 510(k) and CLIA Waiver by Applications with 510(k) RTA review accepted in this fiscal year.
2	Withdrawn prior to SI	Number of submissions that were Withdrawn prior to 90 days.
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days.
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days.
5	SI pending within 90 FDA days	Submissions that are awaiting SI and where 90 days have not yet elapsed.
6	SI pending over 90 FDA days	Submissions that have been under review over 90 FDA days and that do not have an SI.
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior.
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within goal (line 3) divided by the total number of submissions that either had an SI (line 3 and line 4) or did not have an SI but failed the SI goal (line 6 and line 7).



**Table 12.2 Dual 510(k) and CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of Dual 510(k) and CLIA Waiver by Applications accepted in this fiscal year that had an SI
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to SI across all Dual 510(k) and CLIA Waivers with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).



**Table 12.3 Dual 510(k) and CLIA Waiver (without panel review) MDUFA V Decision Performance Goals – Definitions**

#	Measure	Description
1	Eligible for MDUFA V Decision	Number of Dual 510(k) and CLIA Waiver by Applications that were accepted in this fiscal year, and did not have a panel review.
2	Non-MDUFA V Decisions	Number of submissions closed with non-MDUFA V decisions.
3	MDUFA V Decisions	Number of submissions closed with MDUFA V decisions.
4	MDUFA V Decisions within 180 FDA Days	Number of submissions with MDUFA V decisions made within 180 FDA days.
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA V Decision over 180 FDA days	Number of submissions pending MDUFA V Decision for more than 180 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 180 FDA Days	Number of submissions with MDUFA V Decisions within 180 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).



**Table 12.4 Dual 510(k) and CLIA Waiver (with panel review) MDUFA V Decision Performance Goals – Definitions**

#	Measure	Description
1	Eligible for MDUFA V Decision	Number of Dual 510(k) and CLIA Waiver by Applications that were accepted in this fiscal year, and had a panel review.
2	Non-MDUFA V Decisions	Number of submissions closed with non-MDUFA V decisions.
3	MDUFA V Decisions	Number of submissions closed with MDUFA V decisions.
4	MDUFA V Decisions within 320FDA Days	Number of submissions with MDUFA V decisions made within 320 FDA days.
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA V Decision over 320 FDA days	Number of submissions pending MDUFA V Decision for more than 320 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 320 FDA Days	Number of submissions with MDUFA V Decisions within 320 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).



**Table 12.5    Dual 510(k) and CLIA Waiver (without panel review) Time to MDUFA V Decision – Definitions**

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision), and did not have a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 12.6    Dual 510(k) and CLIA Waiver (with panel review) Time to MDUFA V Decision – Definitions**

#	Measure	Description
1	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision, and had a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.



## Section 13 Total Product Life Cycle Advisory Program (TAP)

**Table 13.1 TAP Teleconference Engagement Performance Goal – Definitions**

#	Measure	Description
1	Teleconferences Requested	Number of Teleconferences requested
2	Closed before Teleconference	Number of Teleconferences Requested (line 1) that were closed with a final decision before Teleconference Held (e.g., "Withdrawn by Sponsor/Applicant" (WTDR))
3	Teleconferences Held	Number of Teleconferences Requested (line 1) that had a final decision (e.g., "Teleconference Held" (TCON))
4	Teleconferences Held Within 14 Days	Number of Teleconferences Requested (line 1) that had a final decision (e.g., "Teleconference Held" (TCON)) within 14 days
5	Teleconferences Pending	Number of Teleconferences Requested (line 1) that are under review without a final decision
6	Teleconferences Pending Over 14 Days	Number of Teleconferences Requested (line 1) that are under review without a final decision and where 14 days have elapsed.
7	Current Performance Percent Within 14 Days	Number of Teleconferences Held Within 14 Days (line 4) expressed as a percentage of the sum of the Teleconferences Held (line 3) and Teleconferences Pending Over 14 Days (line 6)



**Table 13.2 TAP Written Feedback (Biocompatibility/Sterility) Performance Goal – Definitions**

#	Measure	Description
1	Written Feedback Requested	Number of Written Feedback Requested on Biocompatibility and Sterility topics(s)
2	Closed before Written Feedback	Number of Written Feedback Requested (line 1) that were closed with a final decision before Email reply (e.g., "Withdrawn by Sponsor/Applicant" (WTDR))
3	Written Feedback Provided	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL))
4	Written Feedback Provided Within 21 Days	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL)) within 21 days
5	Written Feedback Pending	Number of Written Feedback Requested (line 1) that are under review without a final decision
6	Written Feedback Pending Over 21 Days	Number of Written Feedback Requested (line 1) that are under review without a final decision and where 21 days have elapsed.
7	Current Performance Percent Within 21 Days	Number of Written Feedback Provided Within 21 Days (line 4) expressed as a percentage of the sum of the Written Feedback Provided (line 3) and Written Feedback Pending Over 21 Days (line 6)



**Table 13.3 TAP Written Feedback (Other) Performance Goal – Definitions**

#	Measure	Description
1	Written Feedback Requested	Number of Written Feedback Requested on topics(s) other than Biocompatibility and Sterility
2	Closed before Written Feedback	Number of Written Feedback Requested (line 1) that were closed with a final decision before Email reply (e.g., “Withdrawn by Sponsor/Applicant” (WTDR))
3	Written Feedback Provided	Number of Written Feedback Requested (line 1) that had a final decision (e.g., “Email reply” (EMAL))
4	Written Feedback Provided Within 40 Days	Number of Written Feedback Requested (line 1) that had a final decision (e.g., “Email reply” (EMAL)) within 40 days
5	Written Feedback Pending	Number of Written Feedback Requested (line 1) that are under review without a final decision
6	Written Feedback Pending Over 40 Days	Number of Written Feedback Requested (line 1) that are under review without a final decision and where 40 days have elapsed.
7	Current Performance Percent Within 40 Days	Number of Written Feedback Provided Within 40 Days (line 4) expressed as a percentage of the sum of the Written Feedback Provided (line 3) and Written Feedback Pending Over 40 Days (line 6)

**Table 13.4 TAP Pilot Enrollment Data– Definitions**

#	Measure	Description
1	Enrollment Requests Received	Number of TAP Pilot Enrollment Requests received in the fiscal year.
2	Enrollment Requests Accepted	Number of TAP Pilot Enrollment Requests accepted in the fiscal year.
3	Enrollment Requests Not Accepted	Number of TAP Pilot Enrollment Requests not accepted in the fiscal year.
4	Enrollment Requests Pending	Number of TAP Pilot Enrollment Requests still under review.



**Quarterly Update on  
Medical Device Performance Goals  
---- MDUFA V CBER Performance Data ----  
Actions through 31 March 2025**



## Section 1 PMA Original and Panel-Track Supplements - Center Level Metric

**Table 1.1 CBER - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	0	1		
Closed Before RTA Action	0	0	0		
Number with Accepted RTA Review	3	0	1		
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted for Filing Review	0	0	0		
Rate of Submissions Not Accepted for Filing Review	0.00%	N/A	0.00%		

**Table 1.2 CBER - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	0	1		
Number Accepted	3	0	1		
Completed RTF	3	0	1		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	0.00%	N/A	0.00%		

**Table 1.3 CBER - PMA Original and Panel-Track Supplements Substantive Interaction**

### Performance Goal

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	3	0	1		
SI Goal Met	3	0	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	N/A	N/A		

**Table 1.4 CBER - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	3	0	0		
Average Number of FDA Days to Substantive Interaction	88.33	0.00	0.00		
20th Percentile FDA Days to Substantive Interaction	87	0.00	0.00		
40th Percentile FDA Days to Substantive Interaction	88	0.00	0.00		
60th Percentile FDA Days to Substantive Interaction	88	0.00	0.00		
80th Percentile FDA Days to Substantive Interaction	89	0.00	0.00		
Maximum FDA Days to Substantive Interaction	90	0.00	0.00		



**Table 1.5 CBER - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	3	0	1		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision	3	0	0		
MDUFA V Decision Goal Met	3	0	0		
PMAs Pending MDUFA V Decision	0	0	1		
PMAs Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	N/A	N/A		

**Table 1.6 CBER - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	0	0		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision	0	0	0		
MDUFA V Decision Goal Met	0	0	0		
PMAs Pending MDUFA V Decision	0	0	0		
PMAs Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	N/A	N/A		



**Table 1.7 CBER - PMA Original and Panel-Track Supplements (Without Panel Review)**

**Performance Metric - Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA V Decision	3	0	0		
<b>Average FDA Days to MDUFA V Decision</b>	177.00	0.00	0.00		
20th Percentile FDA Days to MDUFA V Decision	175	0	0		
40th Percentile FDA Days to MDUFA V Decision	178	0	0		
60th Percentile FDA Days to MDUFA V Decision	179	0	0		
80th Percentile FDA Days to MDUFA V Decision	180	0	0		
Maximum FDA Days to MDUFA V Decision	180	0	0		
<b>Average Industry Days to MDUFA V Decision</b>	0.00	0.00	0.00		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	0	0		
60th Percentile Industry Days to MDUFA V Decision	0	0	0		
80th Percentile Industry Days to MDUFA V Decision	0	0	0		
Maximum Industry Days to MDUFA V Decision	0	0	0		
<b>Average Total Days to MDUFA V Decision</b>	177.00	0.00	0.00		
20th Percentile Total Days to MDUFA V Decision	175	0	0		
40th Percentile Total Days to MDUFA V Decision	178	0	0		
60th Percentile Total Days to MDUFA V Decision	179	0	0		
80th Percentile Total Days to MDUFA V Decision	180	0	0		
Maximum Total Days to MDUFA V Decision	180	0	0		



**Table 1.8 CBER - PMA Original and Panel-Track Supplements (with Panel Review)****Performance Metric - Time to MDUFA V Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA V Decision	0	0	0		
<b>Average FDA Days to MDUFA V Decision</b>	0.00	0.00	0.00		
20th Percentile FDA Days to MDUFA V Decision	0	0	0		
40th Percentile FDA Days to MDUFA V Decision	0	0	0		
60th Percentile FDA Days to MDUFA V Decision	0	0	0		
80th Percentile FDA Days to MDUFA V Decision	0	0	0		
Maximum FDA Days to MDUFA V Decision	0	0	0		
<b>Average Industry Days to MDUFA V Decision</b>	0.00	0.00	0.00		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	0	0		
60th Percentile Industry Days to MDUFA V Decision	0	0	0		
80th Percentile Industry Days to MDUFA V Decision	0.00	0.00	0		
Maximum Industry Days to MDUFA V Decision	0	0	0		
<b>Average Total Days to MDUFA V Decision</b>	0	0	0.00		
20th Percentile Total Days to MDUFA V Decision	0	0	0		
40th Percentile Total Days to MDUFA V Decision	0	0	0		
60th Percentile Total Days to MDUFA V Decision	0	0	0		
80th Percentile Total Days to MDUFA V Decision	0	0	0		
Maximum Total Days to MDUFA V Decision	0	0	0		

**Table 1.9 CBER - PMA Original and Panel-Track Supplements (Without Panel Review)****Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	3	0	1		
Number with MDUFA V Decision	3	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	N/A	N/A		
Rate of Not Approvable	0.00%	N/A	N/A		

**Table 1.10 CBER - PMA Original and Panel-Track Supplements (with Panel Review)****Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0	0		
Number With MDUFA V Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	N/A	N/A	N/A		



**Table 1.11 CBER - PMA Original and Panel-Track Supplements (Without Panel Review)****Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00		

**Table 1.12 CBER - PMA Original and Panel-Track Supplements (with Panel Review)****Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00		

**Table 1.13 CBER - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	0	0	0		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision	0	0	0		
MDUFA V Decision Goal Met	0	0	0		
PMAs Pending MDUFA V Decision	0	0	0		
PMAs Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	N/A	N/A		

\*Includes submission that went to panel

**Table 1.14 CBER - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	0	0		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision	0	0	0		
MDUFA V Decision Goal Met	0	0	0		
PMAs Pending MDUFA V Decision	0	0	0		
PMAs Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	N/A	N/A		

\*Includes submission that went to panel



## Section 2 PMA 180-Day Supplements - Center Level Metric

**Table 2.1 CBER - PMA 180-Day Supplements Substantive Interaction Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	4	5	4		
SI Goal Met	2	5	2		
SI Goal Not Met	2	0	0		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	50.00%	100.00%	100.00%		

**Table 2.2 CBER - PMA 180-Day Supplements MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	4	5	4		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision	4	4	0		
MDUFA V Decision Goal Met	3	4	0		
Supplements Pending MDUFA V Decision	0	1	4		
Supplements Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	75.00%	100.00%	N/A		

**Table 2.3 CBER - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	5	4		
Number with MDUFA V Decision	4	4	0		
Number of Not Approvable	1	0	0		
Rate of Not Approvable	25.00%	0.00%	N/A		

**Table 2.4 CBER - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	0	0		
Mean FDA Days for Submissions that Missed the Goal	206.00	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	121.00	N/A	N/A		



### Section 3 PMA Real-Time Supplements - Center Level Metric

**Table 3.1 CBER - PMA Real-Time Supplements MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	3	2	1		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision	3	2	1		
MDUFA V Decision Goal Met	3	2	1		
Supplements Pending MDUFA V Decision	0	0	0		
Supplements Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

**Table 3.2 CBER - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	2	1		
Number With MDUFA V Decision	3	2	1		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0%	0%	N/A		

**Table 3.3 CBER - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		



## Section 6 510(k) Center Level Metrics (Excludes Third Party Review)

**Table 6.1 CBER - 510(k) Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	41	33	19		
Closed Before First RTA or TS Action <sup>1</sup>	0	1	0		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	30	26	17		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	11	6	2		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	26.83%	18.75%	10.53%		

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 6.2 CBER - 510(k) Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible for SI	39	30	17		
Deleted or Withdrawn Prior to SI	0	0	0		
SI Within 60 FDA Days	37	30	10		
SI Over 60 FDA Days	2	0	0		
SI Pending Within 60 FDA Days	0	0	7		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	0	1	0		
Current SI Performance Percent Within 60 FDA Days	94.87%	96.77%	100.00%		



**Table 6.3 CBER - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	39	30	10		
Average Number of FDA Days to Substantive Interaction	55.53	56.20	49.20		
20th Percentile FDA Days to Substantive Interaction	51	57	28		
40th Percentile FDA Days to Substantive Interaction	56	58	59		
60th Percentile FDA Days to Substantive Interaction	59	59	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	90	60	60		

**Table 6.4 CBER - 510(k) MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	39	30	17		
Non-MDUFA V Decision	3	1	0		
MDUFA V Decision (SE/NSE)	36	23	7		
MDUFA V Decision Within 90 FDA Days	36	23	7		
510(k)s Pending MDUFA V Decision	0	6	10		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%		



**Table 6.5 CBER - 510(k) Time to MDUFA V Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.33	1.48	1.29		
Number With MDUFA V Decision	36	23	7		
<b>Average Number of FDA Days to MDUFA V Decision</b>	77.33	78.83	60.86		
20th Percentile FDA Days to MDUFA V Decision	69	70	26		
40th Percentile FDA Days to MDUFA V Decision	84	83	51		
60th Percentile FDA Days to MDUFA V Decision	89	86	87		
80th Percentile FDA Days to MDUFA V Decision	90	89	88		
Maximum FDA Days to MDUFA V Decision	90	90	88		
<b>Average Number of Industry Days to MDUFA V Decision</b>	48.92	69.13	7.86		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	0	0		
60th Percentile Industry Days to MDUFA V Decision	0	85	0		
80th Percentile Industry Days to MDUFA V Decision	115	170	17		
Maximum Industry Days to MDUFA V Decision	315	207	34		
<b>Average Number of Total Days to MDUFA V Decision</b>	126.25	148.65	68.71		
20th Percentile Total Days to MDUFA V Decision	81	75	26		
40th Percentile Total Days to MDUFA V Decision	88	87	51		
60th Percentile Total Days to MDUFA V Decision	90	175	87		
80th Percentile Total Days to MDUFA V Decision	90	255	105		
Maximum Total Days to MDUFA V Decision	375	288	122		



**Table 6.6 CBER - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	39	30	17		
Number With MDUFA V Decision	36	23	7		
Number of SE Decision	35	19	5		
Number of NSE Decision	1	4	2		
Number of Withdrawal	2	0	0		
Number of Deleted	1	1	0		
Rate of SE Decision	97.22%	82.61%	71.43%		
Rate of NSE Decision	2.78%	17.39%	28.57%		
Rate of Withdrawal	5.13%	0.00%	0.00%		
Rate of Deleted	2.56%	3.33%	0.00%		

**Table 6.7 CBER - 510(k) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		



**Table 6.8 CBER - LDT 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	0	0	0		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision (SE/NSE)	0	0	0		
MDUFA V Decision Within 90 FDA Days	0	0	0		
510(k)s Pending MDUFA V Decision	0	0	0		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		

**Table 6.9 CBER - Conventional IVD (Non-LDT) 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	8	3	0		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision (SE/NSE)	8	3	0		
MDUFA V Decision Within 90 FDA Days	8	3	0		
510(k)s Pending MDUFA V Decision	0	0	0		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	N/A		



## Section 8 De Novo Center Level Metrics

**Table 8.1 CBER - De Novo Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	1	0	0		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	0	0	0		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted or Failed TS on First Cycle	1	0	0		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	100.00%	N/A	N/A		

1.The data contained in this row should be combined with the data in the row above, “Number Accepted or Passed TS on First Cycle”, to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 8.2 CBER - De Novo MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	1	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA Decision	1	0	0		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		



**Table 8.3 CBER - De Novo Time to MDUFA V Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	2.00	0.00	0.00		
Number With MDUFA Decision	0	0	0		
<b>Average FDA Days to MDUFA Decision</b>	0.00	0.00	0.00		
20th Percentile FDA Days to MDUFA Decision	0	0			
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
<b>Average Industry Days to MDUFA Decision</b>	0.00	0.00	0.00		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
<b>Average Total Days to MDUFA Decision</b>	0.00	0.00	0.00		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	0	0	0		

**Table 8.4 CBER - De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	1	0	0		
Number With MDUFA Decision	0	0	0		
Number With Granted Decision	0	0	0		
Number With Declined Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Deleted	0	0	0		
Rate of Granted Decision	N/A	N/A	N/A		
Rate of Declined Decision	N/A	N/A	N/A		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Deleted	N/A	N/A	N/A		



**Table 8.5 CBER - De Novo Performance Metrics-Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00		

**Table 8.6 CBER - LDT De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA Decision	0	0	0		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		

**Table 8.7 CBER - Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA Decision	0	0	0		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		



## Section 9 Pre-Sub Center Level Metrics

**Table 9.1 CBER - Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	68	62	34		
Interactions for Breakthrough Designated Products & Products Included in STeP	3	1	1		
Number Closed Before First RTA Action	7	1	1		
Number Accepted First RTA Cycle <sup>1</sup>	59	60	33		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	2	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted First RTA Cycle	0	1	0		
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.00%	1.64%	0.00%		

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, “Number Accepted First RTA Cycle” to determine the total number of submissions accepted on the first RTA cycle.

**Table 9.2 CBER - MDUFA V Pre-Sub Performance Goals**

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	61	61	33		
Number with Non-MDUFA Action <sup>3</sup>	3	0	0		
Number with MDUFA Action	58	61	23		
Written Feedback Provided Within Goal	55	61	23		
Number Pending MDUFA Action	0	0	10		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	58	61	33		
Current Performance Percent Within Goal	94.83%	100.00%	100.00%		

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.



**Table 9.3 CBER – MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	58	61	23		
Average FDA Days to Written Feedback	59.38	60.79	60.22		
20th Percentile FDA Days to Written Feedback	55	54	56		
40th Percentile FDA Days to Written Feedback	60	61	59		
60th Percentile FDA Days to Written Feedback	64	65	64		
80th Percentile FDA Days to Written Feedback	69	69	67		
Maximum FDA Days to Written Feedback	72	70	70		

**Table 9.4 CBER - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling  
(for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	0	0	0		
Average Days to Scheduling for Meetings Scheduled After Day 30	0.00	0.00	0.00		

**Table 9.5 CBER - MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required <sup>1</sup>	24	31	10		
Meeting Minutes Submitted Within 15 Days of Meeting	21	26	8		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0		
Meeting Minutes Past 15 Days of Meeting	3	5	2		
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	0	0		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	87.50%	83.87%	80.00%		

1. Number of meetings requested and then held after written feedback is provided.



## Section 10 IDE- Center Level Metric

Table 10.1 CBER - IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	20	15	7		
Average Number of Cycles to IDE Approval or Conditional Approval	1.07	1.00	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.07	0.00	0.00		



**CBER – Annual General Metric Report for BLA/BLA Resubmissions**  
**\*\*Annual Metrics and Goals will be reported in the Annual Report\*\***



## Medical Devices

### Guidance Documents

Pursuant to the MDUFA V Commitment Letter,<sup>1</sup> the table below includes all FDA guidance documents issued in the specified quarter related to the devices program. Pursuant to section 738A(a)(1)(A)(iii) of the FD&C Act, guidance documents that are related to the process for the review of devices and whether they are required by statute or are being issued pursuant to the MDUFA V Commitment Letter are indicated as such.<sup>2</sup> The table also indicates whether a guidance document is on the Center for Devices and Radiological Health's annual agenda of guidance documents (known as the A/B List).<sup>3</sup>

**Table 1: Draft and Final Guidance Documents Related to the Devices Program for FY 2025**

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
1	Q1	Endosseous Dental Implants and Endosseous Dental Implant Abutments - Performance Criteria for Safety and Performance Based Pathway <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/endosseous-dental-implants-and-endosseous-dental-implant-abutments-performance-criteria-safety-and">www.fda.gov/regulatory-information/search-fda-guidance-documents/endosseous-dental-implants-and-endosseous-dental-implant-abutments-performance-criteria-safety-and</a>	10/15/2024	Yes	No	N/A	No
2	Q1	Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-long-term-clinical-neurodevelopmental-safety-studies-neonatal-product-development">www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-long-term-clinical-neurodevelopmental-safety-studies-neonatal-product-development</a>	10/18/2024	Yes	No	N/A	No
3	Q1	510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program-and-third-party-emergency-use-authorization-eua-review">www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program-and-third-party-emergency-use-authorization-eua-review</a>	11/21/2024	No	Yes	Section 2502 of the Food and Drug Omnibus Reform Act (FDORA)	A-List
4	Q1	Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-metallic-bone-screws-and-washers-performance-criteria-safety-and-performance">www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-metallic-bone-screws-and-washers-performance-criteria-safety-and-performance</a>	11/22/2024	Yes	No	N/A	No

<sup>1</sup> [www.fda.gov/media/158308/download](http://www.fda.gov/media/158308/download).

<sup>2</sup> CDRH provides the annotation of "yes" for guidance's that are substantially related to the process. CDRH provides the annotation of "no" for guidance's that contain a minimal amount of guidance related to the process.

<sup>3</sup> [CDRH Proposed Guidance Development | FDA](#)



#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
5	Q1	<sup>4</sup> Orthopedic Non-Spinal Bone Plates, Screws, and Washers - Premarket Notification (510(k)) Submissions <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-bone-plates-screws-and-washers-premarket-notification-510k-submissions">www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-bone-plates-screws-and-washers-premarket-notification-510k-submissions</a>	11/22/2024	Yes	No	N/A	No
6	Q1	<sup>5</sup> Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/transitional-enforcement-policy-ethylene-oxide-sterilization-facility-changes-class-iii-devices">www.fda.gov/regulatory-information/search-fda-guidance-documents/transitional-enforcement-policy-ethylene-oxide-sterilization-facility-changes-class-iii-devices</a>	11/26/2024	Yes	No	N/A	No
7	Q1	Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence">www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence</a>	12/04/2024	Yes	No	N/A	A-List
8	Q1	<sup>4</sup> Global Unique Device Identification Database (GUDID) <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/global-unique-device-identification-database-gudid">www.fda.gov/regulatory-information/search-fda-guidance-documents/global-unique-device-identification-database-gudid</a>	12/17/2024	No	No	N/A	No
9	Q1	Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/protocol-deviations-clinical-investigations-drugs-biological-products-and-devices">www.fda.gov/regulatory-information/search-fda-guidance-documents/protocol-deviations-clinical-investigations-drugs-biological-products-and-devices</a>	12/30/2024	Yes	No	N/A	No
10	Q2	Validation of Certain In Vitro Diagnostic Devices for Emerging Pathogens During a Section 564 Declared Emergency <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/validation-certain-in-vitro-diagnostic-devices-emerging-pathogens-during-section-564-declared-emergency">www.fda.gov/regulatory-information/search-fda-guidance-documents/validation-certain-in-vitro-diagnostic-devices-emerging-pathogens-during-section-564-declared-emergency</a>	01/07/2025	No	No	N/A	No
11	Q2	Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/communications-firms-health-care-providers-regarding-scientific-information-unapproved-uses">www.fda.gov/regulatory-information/search-fda-guidance-documents/communications-firms-health-care-providers-regarding-scientific-information-unapproved-uses</a>	01/07/2025	No	No	N/A	No

<sup>4</sup> This is a Level 2 guidance document as defined in 21 CFR 10.115(c)(2)

<sup>5</sup> This is a Level 1 guidance document that is immediately in effect as defined in section 701(h)(1)(C) of the FD&C Act and 21 CFR 10.115(g)(2).



#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
12	Q2	Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological">www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological</a>	01/07/2025	Yes	No	N/A	No
13	Q2	Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing">www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing</a>	01/07/2025	Yes	No	N/A	A-List
14	Q2	Pulse Oximeters for Medical Purposes - Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-medical-purposes-non-clinical-and-clinical-performance-testing-labeling-and">www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-medical-purposes-non-clinical-and-clinical-performance-testing-labeling-and</a>	01/07/2025	Yes	No	N/A	A-List
15	Q2	Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc">www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc</a>	01/07/2025	No	Yes	Section 2514 of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act	No
16	Q2	Developing Drugs for Optical Imaging <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-drugs-optical-imaging">www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-drugs-optical-imaging</a>	01/08/2025	Yes	No	N/A	No
17	Q2	<sup>4</sup> Premarket Approval Application and Humanitarian Device Exemption Modular Review <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-approval-application-and-humanitarian-device-exemption-modular-review">www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-approval-application-and-humanitarian-device-exemption-modular-review</a>	01/13/2025	Yes	No	N/A	No
18	Q2	<sup>4</sup> Institutional Review Board (IRB) Written Procedures <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-board-irb-written-procedures">www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-board-irb-written-procedures</a>	02/05/2025	No	No	N/A	No



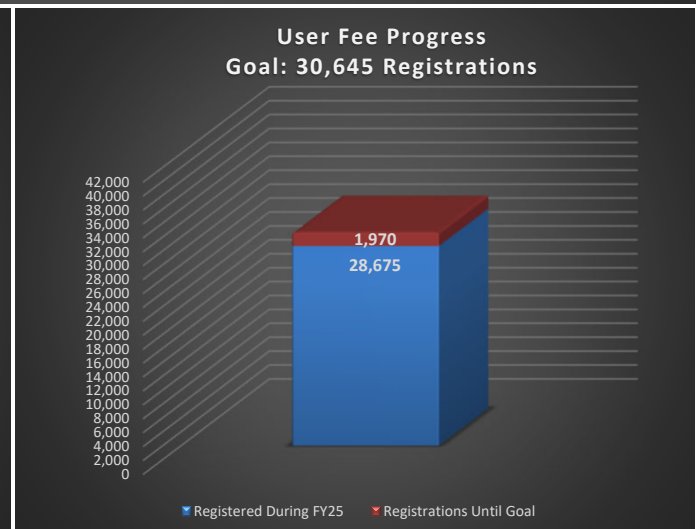
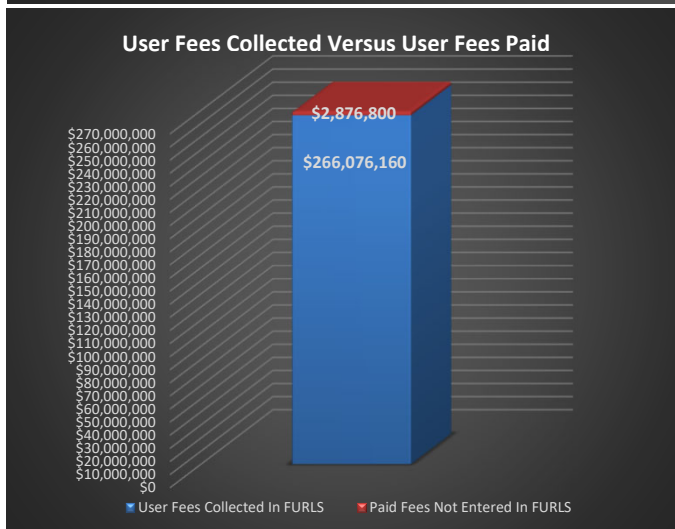
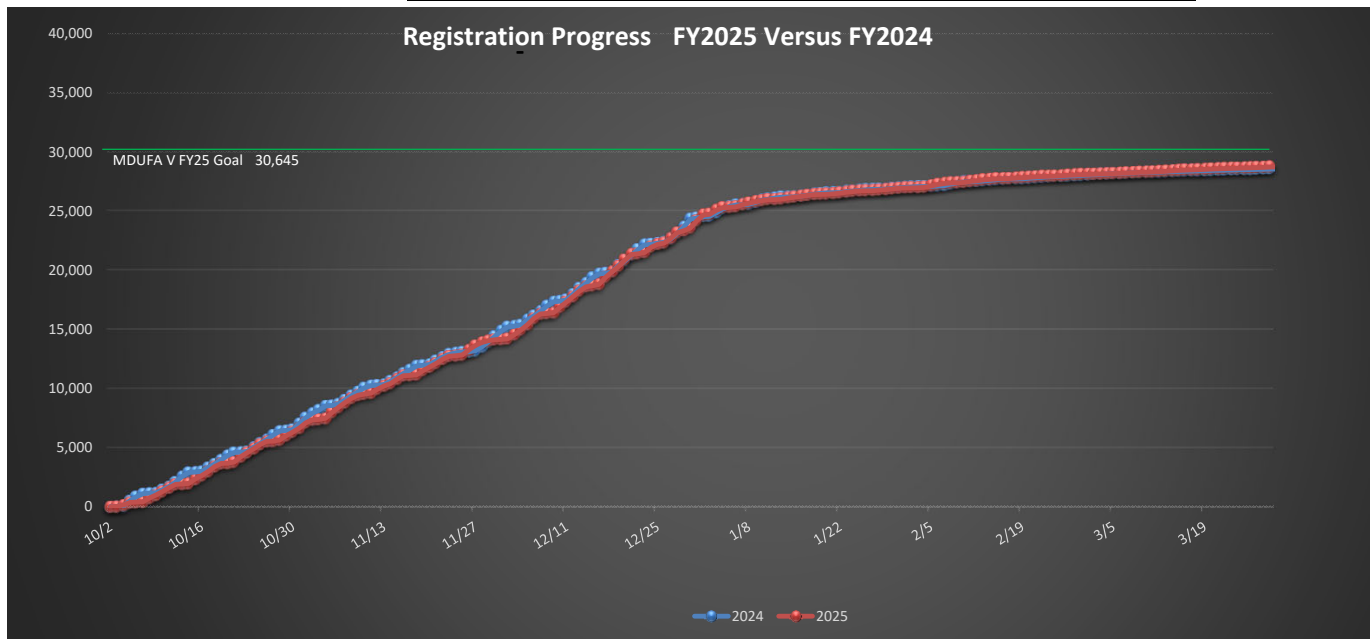
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
19	Q2	<sup>4</sup> Data Standards Catalog <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog">www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog</a>	03/24/2025	Yes	No	N/A	No
20	Q2	<sup>4</sup> Evaluation of Sex-Specific Data in Medical Device Clinical Studies - Guidance for Industry and Food and Drug Administration Staff	03/31/2025	Yes	No	N/A	No



## MDUFA V Registrations - 2nd Quarter Summary FY2025\*

Current Active Registrations by Type	FY25 Q2			FY24 Year End Active Totals			FY25 vs End FY24
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	6,285	11,439	17,724	6,677	12,332	19,009	93.24%
Contract Manufacturer	1,219	1,974	3,193	1,243	1,893	3,136	101.82%
Contract Sterilizer	75	174	249	76	169	245	101.63%
Specification Developer	1,506	540	2,046	1,668	557	2,225	91.96%
Reprocessor of Single Use Devices	20	3	23	34	3	37	62.16%
U.S. Manufacturer of Export Only Devices	114	0	114	127	0	127	89.76%
Repackager/Relabeler	987	171	1,158	1,116	221	1,337	86.61%
Remanufacturer	14	9	23	14	9	23	100.00%
Foreign Exporter/Private Label Distributor		1,020	1,020		1,132	1,132	90.11%
Initial Importer	2,930		2,930	3,357		3,357	87.28%
Unknown	3	12	15	6	11	17	88.24%
<b>Total:</b>	<b>13,153</b>	<b>15,342</b>	<b>28,495</b>	<b>14,318</b>	<b>16,327</b>	<b>30,645</b>	<b>92.98%</b>

\*Note: This data is current as of 03/29/2025





<b>Q2 FY 2025 Medical Device User Fee Collections</b> <b>as of March 31, 2025</b> <b>Excludes Unearned Revenue</b>					
	Receipts	Refunds	Net	Authorized	% of Authorized
Registration Fees	\$266,780,574	-\$610,853	\$266,169,721		
Application Fees	\$57,190,824	-\$513,116	\$56,677,708		
<b>Total</b>	<b>\$323,971,398</b>	<b>-\$1,123,969</b>	<b>\$322,847,429</b>	<b>\$393,710,000</b>	<b>82%</b>
<b>Medical Device User Fee Collection History</b> <b>Excludes Unearned Revenue, Includes Refunds</b>					
MD I	<b>FY 2003</b>	<b>FY 2004</b>	<b>FY 2005</b>	<b>FY 2006</b>	<b>FY 2007</b>
	\$21,620,549	\$26,281,779	\$31,738,775	\$34,425,417	\$28,031,569
MD II	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>
	\$47,794,823	\$56,962,602	\$63,699,312	\$69,720,145	\$65,324,184
MD III	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	\$101,306,430	\$122,346,416	\$136,098,825	\$147,165,318	\$137,782,995
MD IV	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	\$193,896,895	\$208,692,116	\$215,697,178	\$275,338,627	\$269,130,850
MD V	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
	\$322,347,363	\$340,209,427	\$322,847,429		



**MDUFA V Commitment Letter - VI. Performance Reports**  
**2.12. Number of discretionary fee waivers or reductions granted by type of submission<sup>1/</sup>**

<b>CDRH Data 2nd Quarter FY 2025 by Submission type</b>	<b># Waived</b>	<b># Reduced</b>
<b>Full Fee applications<sup>2/</sup></b>	1	0
PMA	1	0
PDP	0	0
PMR	0	0
BLA		
BLA efficacy supplement		
<b>Panel Track Supplements</b>	0	0
<b>De Novo Classification</b>	2	25
<b>180-Day Supplements</b>	1	3
<b>Real-Time Supplements</b>	2	7
<b>510(k)s</b>	25	929
<b>30-day Notices /135 day supplements*</b>	2	11
<b>513(g)s</b>	0	29
<b>PMA Annual Report</b>		
<b>Total</b>	<b>33</b>	<b>1,004</b>

<sup>1/</sup> User fees may be waived for several reasons, including but not limited to: the submitter is a State or Federal Government entity who does not intend to distribute the device commercially; the proposed conditions of use for the device involved are solely for a pediatric population; and, the submitter is a small business submitting their first premarket approval application or premarket report. User fees are reduced for small businesses. 510(k)s reviewed through the Third Party Review program are not included because FDA does not collect user fees for 510(k)s reviewed through that program. Counts are cumulative for the Fiscal Year.

<sup>2/</sup> As specified in the MDUFA V Commitment Letter, BLAs, BLA efficacy supplements, and other CBER data will be reported annually.

**\*135-day supplements were initially received and paid as 30-day notices; totals are combinations of both cohorts**