December 6, 2023

BY ELECTRONIC SUBMISSION

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Comments Regarding *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission—Draft Guidance for Industry and Food and Drug Administration Staff* (Docket # FDA-2023-D-3134)

To Whom It May Concern:

Thank you for the opportunity to submit to the FDA these comments on the recent draft guidance document titled *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission—Draft Guidance for Industry and Food and Drug Administration Staff*[1] on behalf of Brooke & Associates.[2]

Brooke & Associates is a boutique law and advisory firm that provides legal and consulting services to innovative medical device, digital health, and digital therapeutics companies across the globe and at various stages of commercialization. We advise clients of all sizes and clinical, therapeutic, and technological domains to address issues across a broad spectrum—from counseling on compliance with legal and regulatory requirements to providing practical guidance on product-specific market authorization strategies to supporting post-market surveillance activities. Our team represents a diverse set of stakeholders reflective of the evolving device industry and includes attorneys, scientists, engineers, clinical and regulatory affairs professionals, government affairs professionals, and former FDA personnel. Our firm has a particular focus on hardware and software medical devices incorporating wearable sensors, artificial intelligence/machine learning, and virtual, augmented, and mixed reality technologies. In this domain, we have served as an advocate for development of smart regulatory policy for more than a decade. To that end, we respectfully submit the comments in this letter and the attached Table 1 for consideration by the Agency during its effort to finalize the guidance.

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[1] U.S. FOOD & DRUG ADMIN., BEST PRACTICES FOR SELECTING A PREDICATE DEVICE TO SUPPORT A PREMARKET NOTIFICATION [510(K)] SUBMISSION—DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2023), *available at* https://www.fda.gov/media/171838/download [hereinafter BEST PRACTICES DRAFT GUIDANCE].

[2] These comments solely represent the opinions of Brooke & Associates and do not represent the views of any of the firm's clients.

While we appreciate the FDA's effort to describe approaches that device manufacturers can take to determine an appropriate predicate device as part of its premarket notification submission preparation, we believe that it is inappropriate to refer to the recommendations as "best practices" and that the "recommendations" described in the guidance are, in fact, unduly burdensome requirements that are beyond the scope of the Agency's legal authority in regards to, among other things, the documentation it may request as part of a premarket notification submission.

The FDA begins the substantive portion of the guidance by providing a summary of the 510(k) process. Unfortunately, the Agency fails to describe the least burdensome requirement that is established in the Federal Food, Drug, and Cosmetic Act (the "Act" or "FD&C Act")[3] and legally restricts what the FDA can request as part of a premarket notification submission. Specifically, Section 513(i)(1)(D) states that the FDA "shall only request information that is necessary to making substantial equivalence determinations."[4] The FD&C Act further explains that the FDA "shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly." [5] In establishing this "least burdensome" provision, Congress specifically defined the term *necessary* to mean "the minimum required information that would support a determination of substantial equivalence . . . ."[6] In other words, the FDA is prohibited by law from requesting, demanding, or otherwise creating an expectation that device manufacturers submit in a premarket notification submission package any information that is not absolutely required to evaluate whether the subject device is substantially equivalent to a predicate. By requiring that device manufacturers provide information related to, for example, products that the company excluded as a predicate option, the Agency is demanding information that is wholly irrelevant to the substantial equivalence determination. Likewise, information related to the process by which the predicate device was selected is also irrelevant to the substantial equivalence determination. Hence, the FDA is legally prohibited from requesting such information. **We recommend that the Agency explain in the guidance the least burdensome obligations and remove any recommendation or requirement that is inconsistent with the least burdensome provisions of the FD&C Act.**

The Agency's stated goal in this guidance is to "modernize" the 510(k) program and "promot[e] innovation and improv[e] safety by driving innovators toward reliance on more modern predicate devices or objective performance criteria when they seek to bring new devices to the market and ultimately to patients."[7] The Agency's reason for pushing device manufacturers to rely on predicate devices that the FDA considers to be "modern" is that "it believes that newer devices should be compared to the benefits and risks of more modern technology."[8] Unfortunately, the Agency offers no evidence to support this belief. To put this into context, the FDA would never allow a device manufacturer to state that its device has better performance characteristics than another product on the market simply on the manufacturer's belief; indeed, the Agency would rightly require the device manufacturer to substantiate such a claim with scientifically sound evidence. For some reason, however, the public is expected to simply take the FDA's belief that its efforts to "modernize" the 510(k) program, including expecting industry to provide the

[3] 21 U.S.C. § 301 et seq.
[4] *Id.* § 360c(i)(1)(D)(i).
[5] *Id.*
[6] *Id.* § 360c(i)(1)(D)(ii).
[7] BEST PRACTICES DRAFT GUIDANCE at 3.
[8] *Id.*

information in this guidance, is in the best interest of the public without presenting any evidence whatsoever to support the claim. In fact, the burden imposed on device manufacturers may result in delayed patient access to critical medical devices.

As the FDA notes, the Agency tried in 2019 to publicly shame device manufacturers into using predicates that were no more than 10 years old but that proposal was slammed by industry as not only inappropriate from a scientific and technological perspective but legally unsupportable. As such, the Agency wisely moved away from that proposal, acknowledging that "focusing only on older predicates may not optimally promote safer and more effective devices."[9] It its place, the FDA has proposed the contents of this guidance because it "believes that it may be more appropriate to modernize the 510(k) process with respect to the use of predicate devices by focusing on utilizing best practices when selecting a predicate device rather than just their age."[10] Again, the FDA offers no evidence to support this conclusion beyond a statement of its belief and fails to discuss the potential risks associated with this new policy.

More importantly, the FDA does not have the legal authority to "modernize" the 510(k) program by limiting what types of predicate devices a manufacturer can rely upon beyond what is stated in the FD&C Act. As the Agency indicates, the substantial equivalent decision is based on a comparison of the subject device to a predicate device.[11] The only statutory restrictions that affect the ability to rely upon a specific predicate device are situations where:

1) the subject device has a different intended use from the identified predicate device;[12]
2) the subject device has the same intended use as the identified predicate device but different technological characteristics that raise different questions of safety or effectiveness;[13]
3) the predicate device has been "removed from the market at the initiative of the [FDA]",[14] or
4) the predicate device has been "determined to be misbranded or adulterated by a judicial order."[15]

Any legally marketed device that has the same intended use and same or similar technological characteristics as the subject device may be relied upon as a predicate device so long as a) any technological differences do not raise different questions of safety or effectiveness, and b) the legally marketed device has neither been removed from the market at the initiative of the FDA nor determined to be misbranded or adulterated by a judicial order. The FDA rarely takes the initiative to remove a device from the market; typically, corrections or removals that constitute a recall are almost always voluntary, which means that it's taken at the initiative of the device manufacturer not the Agency. Likewise, the FDA rarely obtains a judicial order determining that a device is misbranded or adulterated. Hence, it is an extremely rare occasion that a legally marketed device that has the same intended use and same or similar technological characteristics as the subject device could not serve as a predicate device for purposes of the premarket notification. To be sure, the law simply requires that the subject device manufacturer to demonstrate substantial

[9] *Id.*
[10] *Id.* at 4.
[11] 21 U.S.C. § 360c(i)(1)(A).
[12] *Id.* § 360c(i)(1)(A)(i).
[13] *Id.* § 360c(i)(1)(A)(ii).
[14] *Id.* § 360c(i)(2).
[15] *Id.*

equivalence to ***a*** legally marketed device, not the ***best*** or ***most modern*** medical device. The FDA, however, has proposed (in contravention of its statutory authority) to raise the bar for what constitutes a predicate device upon which a subject device manufacturer can rely upon for demonstrating substantial equivalence. **We recommend that the FDA describe in the guidance the minimum legal requirements for selecting a predicate device and clarify that any recommendations in the guidance that increase the expectations on the predicate device beyond those minimum requirements may not be a basis upon which the Agency can refuse to accept a premarket notification or to determine that the subject device is not substantially equivalent to the selected predicate.**

Beyond the more general comments described above, we have provided a number of line-item comments in Table 1 attached.

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Thank you in advance for your time and consideration of these comments. If you have any questions or require additional information, please do not hesitate to contact me via phone or email at the contact information provided below.

Sincerely yours,

DocuSigned by:
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Table 1: Specific Line-Item Comments on the Best Practices Draft Guidance

#	Page/Line #	Draft Guidance Language	Comments
1	Page 3, Line 66	N/A	The FDA should summarize the least burdensome requirements established in Section 513(i)(1)(D) of the FD&C Act and clearly indicate whether the Agency believes that the recommended information in this guidance is "the minimum required information that would support a determination of substantial equivalence . . . ." *Id.* § 360c(i)(1)(D)(ii).
2	Page 4, Lines 111-112	FDA believes that identification of the characteristics of predicate devices used to support a 510(k) submission in the accompanying 510(k) Summary may provide additional transparency to the public for devices subject to 510(k) requirements.	Providing information about the selected predicate (as well as the subject device) has long been required by regulation. Specifically, 21 C.F.R. § 807.92(a) requires the 510(k) Summary to include the "identification of the legally marketed device to which the submitter claims equivalence" and "a summary of the technological characteristics of the new device in comparison to those of the predicate device." However, nothing in the regulation nor in the FD&C Act requires a device manufacturer to submit information about *potential* predicate devices that were not selected to serve as *the* predicate for purposes of demonstrating substantial equivalence. Hence, creating an expectation that device manufacturers identify other devices that are not the predicate device is unlawful in that it exceeds the minimally required information to determine substantial equivalence. On a more practical level, such a requirement could be an endless endeavor as there may be far too many other devices to identify. Attempting to satisfy this requirement may result in undue delays in submissions of premarket notifications, which in turn would result in delays in patient access to such devices. Furthermore, device manufacturers may not know what constitutes *enough* information about the other devices that were not selected as the predicate or know how many of the other devices need to be included in the 510(k) Summary. Including information about devices that are neither the subject device nor the predicate in the 510(k Summary will more likely than not create confusion for the public as opposed to engendering the additional transparency that the Agency professes to desire. Finally, the FDA has historically not consistently and reliably enforced its existing requirements with regards to the content of the 510(k) Summary (or a device manufacturer's obligations with respect to the 510(k) Statement) and there's no reason to believe that device manufacturers will comply with this new expectation (as a result of ignorance, confusion, or malicious intent) or that the FDA will enforce the requirement that device manufacturers provide information about the other devices not selected as the predicate, creating inconsistency and further confusion for the public.

#	Page/Line #	Draft Guidance Language	Comments
3	Page 5, Lines 137-140	When considering the selection of predicate devices during 510(k) submission preparation, submitters should consider the list of legally marketed devices that they believe have the same intended use as the subject device and when any differences in technological characteristics do not raise different questions about safety and effectiveness, hereafter referred to as a "valid predicate device."	This statement is confusing. The statement effectively defines "a valid predicate device" (which should refer to one product) as a list of legally marketed devices (referring to more than one product). To avoid confusion, we recommend properly defining the term "valid predicate device" as referring to a single product rather than a list of products.
4	Page 6, Lines 149-159	FDA recommends the submitter include within their 510(k) submission how they used the best practices identified in this guidance in selecting the predicate device(s) used to support the 510(k) submission. For example, if a valid predicate device consistent with the best practices identified in this guidance is not available, FDA recommends describing in the 510(k) submission how any known concerns with the valid predicate device have been mitigated with the subject device (e.g., design features, performance testing). FDA also recommends that the submitter summarize how the best practices were utilized in the selection of the predicate device used to support the 510(k) submission in the 510(k) Summary (See Section VI of this guidance). These recommendations are intended to aid the submitter in selecting a predicate for their device and help provide additional transparency to the public in the 510(k) summary if the 510(k) submission is cleared by FDA.	Assuming the proper definition of "a valid predicate device" is a single legally marketed device that the subject device manufacturer believes to have the same intended use as the subject device and the same or sufficiently similar technological characteristics so as to not raise different questions of safety or effectiveness, this statement is confusing because if such a valid predicate device does not exist, it is not clear how a substantial equivalence determination could ever be achieved. In addition, as noted in these comments, the FDA does not have the legal authority to request this information. The FDA should clarify whether it intends to reject a submission (e.g., through at the Refuse-to-Accept stage) or issue a Not Substantially Equivalent determination if this information is not included in the premarket notification submission.

#	Page/Line #	Draft Guidance Language	Comments
5	Page 7, Lines 179-185	FDA recommends selecting a valid predicate device that was cleared using well-established methods. These methods include those from a currently FDA-recognized voluntary consensus standard, an FDA guidance document, a qualified medical device development tool (MDDT), or a widely available and accepted method published in the public domain or scientific literature for the context of use, or found acceptable through the submitter's own previous premarket submission. FDA recommends prioritizing predicate devices with methods developed within a consensus environment, and those subject to public comment or peer review.	Again, the FDA does not have the legal authority to limit the scope of the predicate devices to those that were "cleared using well-established methods." While in some instances it may be advantageous to rely upon such a predicate device, there may also be many reasons why it is appropriate and legally acceptable to rely on a predicate device that does not meet this new "cleared using well-established methods" standard that the FDA has created. It is the prerogative of the subject device manufacturer to choose the predicate device and the FDA is obliged to grant market authorization via the 510(k) pathway if the device manufacturer meets the legal requirements for demonstrating substantial equivalence. The FDA should not be creating undue burden or new requirements that are not stated in the FD&C Act. The FDA should explain the legal basis for creating this new standard for determining whether a predicate device is acceptable. In addition, the FDA should clarify whether it intends to reject a submission (e.g., through at the Refuse-to-Accept stage) or issue a Not Substantially Equivalent determination if a predicate device that is relied upon for the substantial equivalence analysis was not cleared using the well-established methods defined in this guidance.
6	Page 7, Lines 186-189	FDA believes that when selecting a valid predicate device, submitters should consider how much information is available regarding the test method(s) used in support of the predicate device's 510(k) clearance and whether those methods continue to be appropriate for evaluating the subject device.	This statement gets to the crux of the 510(k) problem, which is that many times there is insufficient information in the public domain about the predicate devices. The FDA, however, has access to a trove of information about all medical devices that have been granted market authorization. Rather than limit the predicate options, the FDA should make available more information about predicate devices so that a comprehensive predicate analysis can be conducted. It seems incongruous that the public has access to every daily Federal Register notice going back to 1936 (when the Federal Register was first published) but does not have access to the 510(k) Summaries for medical devices that were granted market authorization in some instances as late as the late 2000s. The FDA should publish all 510(k) Summaries in its possession so that a comprehensive predicate analysis can be conducted. Moreover, the FDA should work to publish full 510(k) submission packages consistent with the FOIA requirements for maintaining confidential commercial and trade secret information. In many cases the FDA hides information that should otherwise be publicly available. For example, in instances where companies no longer exist and claims of confidential/trade secret information can no longer be maintained, such information should be made publicly available. Likewise, when the FDA provides 510(k) documentation to someone in response to a FOIA request, the Agency should publish the documentation on its website so that the public has access to that information. Doing so would allow others to use that information for purposes of their predicate analysis, resulting in more meaningful transparency and better substantial equivalence determinations.

#	Page/Line #	Draft Guidance Language	Comments
7	Page 8, Lines 199-202	FDA considers it a best practice to select a predicate that was cleared using well-established methods, as this will continue to advance the 510(k) Program, by encouraging the evolution of safer and more effective medical devices in the 510(k) program over time, and ensure that the subject device is evaluated using updated scientific methods whenever possible.	This guidance appears to be creating a new standard that is loosely defined and not specific to any particular product. The FDA should clarify the basis for this new standard (or explain how this is consistent with the existing, purportedly arcane 510(k) Program) and how the Agency intends to ensure consistency in its application. The FDA's statement here has a significant impact beyond the scope of its stated purposes (i.e., to "encourag[e] the evolution of safer and more effective medical devices in the 510(k) program" and to "ensure that the subject device is evaluated using updated scientific methods"). By claiming that it is a best practice to select a predicate that was cleared using well-established methods implies that a device would be inferior if it demonstrates substantial equivalence to a predicate that does not meet this nebulous standard, which would include most devices that were cleared prior to the creation of this expectation in this guidance. Such a statement can have real and substantial financial impacts on, for example, reimbursement potential and company valuation and can create real litigation risk for device manufacturers by enabling plaintiff arguments that products did not follow purported best practices when selecting a predicate device. The FDA should articulate the potential risks of this new standard and remove any reference to the proposed approach as being a "best practice".
8	Page 8, Lines 206-210	FDA considers it a best practice to select a valid predicate device that continues to perform safely and as intended by the manufacturer during use in its intended environment of use whenever possible. FDA recommends selecting a valid predicate device after considering how any reported medical device-related adverse events, malfunctions, or deaths may have a role in the safety and effectiveness of the device.	As noted above, the use of the term "best practice" in the context of the proposed approaches to selecting a predicate device can have significant legal and financial implications for device manufacturers. The FDA should remove any such reference in this guidance. Furthermore, the FDA does not have the legal authority 1) to require medical device manufacturers to select a predicate device after considering how any reported medical device-related adverse events, malfunctions, or deaths regarding the predicate device may have a role in the safety and effectiveness of the subject device or 2) to limit, restrict, or otherwise reject the predicate for lack of such a consideration. Such information is not required by statute, is not required under the current 510(k) Program, and is not minimally required to determine substantial equivalence. Furthermore, the adverse events, malfunctions, and deaths related to a predicate device are not, by default, inherently relevant to the subject device and, from a practical perspective, may be extremely difficult to analyze given the dearth of information that is typically provided in such reports. Unfortunately, the Agency has a tendency to use the publicly available adverse event databases as a sword and shield—arguing, on the one hand, that the databases are important for predicate selection and, on the other hand, that the databases do not represent the full picture of risk such that, if there are few reported adverse events associated with a particular product, the true picture of the risk must be worse if the Agency believes it to be so. The FDA should explain the legal basis upon which this requirement is established and explain how such a requirement can be practically applied.

#	Page/Line #	Draft Guidance Language	Comments
9	Pages 8-9, Lines 219-234	Once the submitter has identified a list of valid predicate devices, FDA recommends conducting a search for any reported injury, deaths, or malfunctions using the following FDA databases: • Manufacturer and User Facility Device Experience (MAUDE) Database; • Medical Device Reporting (MDR) Database; and • MedSun Reports Database. FDA recommends searching each of the above databases for any reports of unexpected injury, deaths, or malfunctions associated with the available valid predicate devices. . . . If another valid predicate device is not available, FDA recommends that the submitter describe in the 510(k) submission how the subject device mitigates the known concerns with the predicate device used to support the 510(k) submission.	The FDA is effectively establishing a requirement that the subject device manufacturer rely on a predicate device that has no reports of injury, deaths, or malfunctions or, if no such predicate device is available, justify to the Agency in the 510(k) submission how the subject device manufacturer has mitigated concerns related to reports of injury, deaths, or malfunctions associated with the predicate device. This expectation is problematic for multiple reasons. First, such a requirement is not legally founded. The FDA does not have the authority to dictate such an approach or to demand such information as this information is not necessary to evaluate the substantial equivalence of the product as defined in the FD&C Act. Second, reports of injury, deaths, or malfunctions related to the predicate device does not mean that the subject device would have the same failure modes or malfunctions that could result in patient harm as reported for the predicate device. This is particularly true in the software context, where a bug that results in a malfunction in one product does not mean that such a bug would exist or would even trigger the same malfunction in the subject device. Finally, the information necessary to conduct the analysis that the FDA is demanding is almost invariably not available, making any such analysis largely an exercise in futility. The FDA should justify imposing this undue burden on medical device manufacturers and explain the legal basis for such a requirement. If the Agency believes that this "recommendation" is not a requirement (an argument it often relies upon in responding to public comments on guidance documents), the FDA should clarify that a 510(k) submission would not be rejected if such an analysis is not included in the 510(k) submission and that the failure to include such an analysis would not be a basis for determining that a subject device is not substantially equivalent to the selected predicate device.
10	Page 9, Lines 237-239	FDA recommends selecting a valid predicate device that does not have unmitigated use-related or design-related safety issues, including consideration of emerging signals or safety communications.	This statement presupposes that the subject device manufacturer would have access to such information. Unless the FDA intends to disclose such information to the subject device manufacturer or the public at large—which the Agency is undoubtedly unwilling to do if not legally prohibited from doing—this requirement is impossible to achieve. The FDA should explain how it expects device manufacturers to gain access to unmitigated use-related or design-related safety issues that are proprietary and specific to the predicate device manufacturer.
11	Page 9, Lines 264-266	FDA considers it a best practice to select a valid predicate device that is not associated with emerging signals or safety communications that relate to unmitigated use-related or design-related safety issues whenever possible.	Again, the FDA should avoid using the term "best practice" for the reasons stated above. Furthermore, the Agency should explain how it expects device manufacturers to gain access to unmitigated use-related or design-related safety issues that are proprietary and specific to the predicate device manufacturer. Finally, the FDA should justify the legal basis for this requirement, explaining in particular why this information is necessary to determine substantial equivalence.

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12	Page 10, Lines 269-270	FDA recommends selecting a valid predicate device that has not been subject to a design-related recall.	As noted above, the FDA does not have the legal authority to require such information as part of the 510(k) submission because, again, this information is not necessary to support the substantial equivalence determination. The FDA should explain the legal basis for this requirement and why expecting such information meets the least burdensome obligation.
13	Page 10, Lines 281-287	In some instances, the underlying root cause of the design related issues identified as part of a design-related recall may not be available or a correction of these design-related issues may not be possible. Further, although the methods and performance data provided in the 510(k) submission for the valid predicate device subject to a subsequent design-related recall were sufficient to support a substantial equivalence determination at that time of 510(k) clearance, utilization of such a valid predicate device may not be ideal to use for future 510(k) submissions.	The FDA understates how often information about the underlying root cause of a design-related issue identified as part of a design-related recall is not available. In addition, the Agency ignores the fact that the design-related issue associated with the predicate device may not even be relevant to or appropriate for the subject device. Most concerningly, though, the FDA seems to be establishing an extremely high bar by expecting a subject device to rely upon an "ideal" predicate device. The FD&C Act does not authorize the FDA to require reliance upon the "best" or "ideal" predicate device. Indeed, the law does not authorize the FDA to dictate anything about the predicate device other than the four specifications relating to 1) the intended use, 2) the technological characteristics, 3) whether the predicate has been removed from the market *at the initiative* of the FDA, or 4) whether the predicate has been determined to be misbranded or adulterated *by a judicial order*.

14	Page 11, Lines 324-328	FDA recommends that submitters include a narrative explaining their selection of the predicate device(s) used in support of the 510(k) submission in their draft 510(k) Summary submitted with their original 510(k). FDA recommends this narrative include a discussion of how the best practices described in Section V of this guidance were used to select the predicate device(s) proposed for use in the 510(k) submission.	The legal requirements for the content of a 510(k) Summary are defined in Section 513(i)(3) of the FD&C Act and 21 C.F.R. § 807.92. The statute requires the 510(k) Summary to contain with respect to the subject device "an adequate summary of any information respecting safety and effectiveness" and "detailed information regarding data concerning adverse health effects" associated with the subject device. 21 U.S.C. § 360c(i)(3)(A)-(B). The regulation interpreting that provision of the statute states that, with respect to the predicate device, only its identification must be provided. 21 C.F.R. § 807.92(a)(3). Any technological differences between the subject and predicate device must be described as well. *Id.* § 807.92(a)(6). The regulation does not, however, require a narrative explaining the reasons for the predicate selection nor does it require a discussion of the process for selecting the predicate. The regulation does include a catchall provision that states the 510(k) Summary shall contain "[a]ny other information reasonably deemed necessary by the agency." *Id.* § 807.92(d). In establishing this regulatory requirement, the Agency explained that the 510(k) Summary must include "any descriptive data about the [predicate] device that are necessary to understand the characteristics of the device to which the [subject] device is being compared." 59 Fed. Reg. 64,287, 64,288 (Dec. 14, 1994). The information required by this portion of the guidance goes beyond "descriptive data" that are "necessary to understand the characteristics" of the predicate device. Indeed, this new requirement burdens the device manufacturer with including a description of the predicate selection process, which 1) is not "descriptive data" and 2) has nothing to do with the technological characteristics of the predicate device. In fact, this information likely contains confidential commercial information about the subject device that is legally protected from disclosure. Given that recommendations in guidance documents are purportedly not considered requirements, the FDA should clarify whether it believes the narrative described in this guidance is necessary to be included in the 510(k) Summary. Furthermore, the FDA should clarify whether failing to include in the narrative explanation of the predicate selection process would result in the refusal to accept the premarket notification submission or could result in a determination that the subject device is not substantially equivalent to the selected predicate. If the Agency believes the that this information is necessary, it should provide an explanation as to the basis for that conclusion and should ensure consistent application of this requirement to ensure that all 510(k) Summaries contain the requisite information. Finally, the FDA should keep in mind that over-burdening the 510(k) Summary will result in more device manufacturers selecting to file a 510(k) Statement, whereby no information about the device will be publicly available because, from a practical perspective, many companies use the 510(k) Statement as a means to prevent disclosure of the information that the law requires to be made available to the public. The FDA has limited resources to enforce the requirement to disclose information upon request when a device manufacturer chooses to

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			issue a 510(k) Statement instead of the 510(k) Summary. Hence, this requirement may have the complete opposition effect than that which the Agency desires and may result in less publicly available information about predicate devices.
15	Pages 11-12, Lines 332-335	When a submitter cannot identify a valid predicate device(s) that is consistent with any of the best practices discussed in Section V of this guidance, FDA recommends that the submitter include a statement in their 510(k) Summary that a valid predicate that is consistent with the best practices was not available	As noted above, such a requirement is not legally supportable as such information is not descriptive data that are necessary to understand the characteristics about the predicate device. Imposing this requirement will likely result in less transparency because more companies will elect to issue the 510(k) Statement as opposed to stating in the 510(k) Summary that the predicate that was relied upon is somehow deficient or inconsistent with some ill-defined best practice standard.