

From: [Monica Bravo Martinez](#)
To: [CBI Regulatory](#)
Subject: FW: Registration Number 1835959: Successful 2026 Medical Device Establishment Registration
Date: Thursday, December 4, 2025 4:41:08 PM
Attachments: [SignatureBlockLogo.png](#)

FYI- Establishment Registration renewed.

Kind regards,

Monica A. Bravo, MBA, RAC-Global Devices, RCC-EU MDR
Regulatory Affairs Manager
Cook Biotech Incorporated d/b/a Evergen
Office: +1 765-497-3355
Direct line: +1 765-807-1982
Web: www.evergenbio.com

From: CDRH Registration and Listing <reglist@CDRH.FDA.GOV>
Sent: Tuesday, December 2, 2025 7:04 PM
To: Monica Bravo Martinez <mbravo@rtix.com>
Subject: Registration Number 1835959: Successful 2026 Medical Device Establishment Registration

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe. Check the URL and Email ID carefully before clicking or responding. Non-compliance with Evergen's policies will result in appropriate disciplinary action.



Dear Monica Bravo:

This e-mail provides confirmation that the annual registration for the following medical device establishment has been successfully completed for 2026:

Registration Number: 1835959
Owner Operator Number: 9031415
COOK BIOTECH, INC.
1425 INNOVATION PLACE
West Lafayette, IN 47906
UNITED STATES

If you do not see a registration number assigned to the establishment and your establishment previously had one, please send an email to reglist@cdrh.fda.gov and include the registration number you believe is assigned to your establishment. We will review and determine if a

duplicate registration has been created for your establishment.

Your registration is valid until December 31, 2026. Registration for 2027 will be conducted between October 1 and December 31, 2026.

Please note that registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

Should you have any questions, please send an e-mail to the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov.

CDRH Registration and Listing Helpdesk
Imports & Registration and Listing Team
Division 2 Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Tel: 301-796-7400, Option 1

Email: reglist@cdrh.fda.gov





 **Help** (./help/index.html)

DRLM Home (mainMenu.htm)

✓ Facility

✓ Products Listing

Annual Registration Successful

Facility: COOK BIOTECH, INC., West Lafayette, Indiana, UNITED STATES

You have successfully updated your registration and listing information for 2026.

Your registration will be valid through Dec 31, 2026.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2026.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 9031415.

Facility Information

Registration Number:

1835959

Initial Importer:

N

Facility Name:

COOK BIOTECH, INC.

Legal Name:

Address:

**1425 INNOVATION PLACE,
West Lafayette, Indiana, 47906, UNITED STATES**

DUNS Number:

Foreign Trade Zone:

N

Facility URL:

<http://www.cookbiotech.com>

Other Business Trade Name(s):

Establishment located on a campus:

Owner/Operator Information

Owner/Operator Number:
9031415

Contact Name:
Monica A Bravo

Company:
COOK BIOTECH, INC.

Address: 1425 INNOVATION PLACE, --
West Lafayette, INDIANA, 47906, UNITED STATES

Telephone:
765 - 4973355

Fax:
-

E-mail: mbravo@rtix.com

DUNS Number:

Official Correspondent Information

Contact Name:
Monica A Bravo

Company:
COOK BIOTECH, INC.

Address: 1425 INNOVATION PLACE, --
West Lafayette, INDIANA, 47906, UNITED STATES

Telephone:
765 - 4973355

Fax:
-

E-mail: mbravo@rtix.com

DUNS Number:

Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
D023559	K034039		FTM	Mesh, surgical	Manufacturer
D211580	K132660		JXI	CUFF, NERVE	Manufacturer
D537084	K232646		KHJ	POLYMER, ENT SYNTHETIC-POLYAMIDE (MESH OR FOIL MATERIAL)	Manufacturer
D516008	K231708		JXI	CUFF, NERVE	Contract Manufacturer

D250162	K150594		KHJ	POLYMER, ENT SYNTHETIC- POLYAMIDE (MESH OR FOIL MATERIAL)	Manufacturer
D250161	K152033		KGN	Wound dressing with animal-derived material(s)	Manufacturer
D336804	K181038		PSQ	Intracardiac patch or pledget, biologically derived	Contract Manufacturer
D250163	K142887		FTM	Mesh, surgical	Manufacturer
D264961	K152127		DXZ	PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE	Contract Manufacturer
D220954	K133011		FTM	Mesh, surgical	Manufacturer
			OWV	Mesh, surgical, collagen, diaphragmatic hernia	
D083049	K082682		FTM	Mesh, surgical	Manufacturer
D251027	K905766		GBX	CATHETER, IRRIGATION	Manufacturer
D025031	K980431		FTM	Mesh, surgical	Manufacturer
D266997	K160869		GXQ	DURA SUBSTITUTE	Manufacturer
			FTM	Mesh, surgical	
D252084		510(k) exempt	HFS	SHIELD, NIPPLE	Manufacturer
D252085		510(k) exempt	HWT	TEMPLATE	Manufacturer
D266120	K161000		KHJ	POLYMER, ENT SYNTHETIC- POLYAMIDE (MESH OR FOIL MATERIAL)	Manufacturer
D223314	K051405		DXZ	PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE	Contract Manufacturer

D223315	K063349		DXZ	PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE	Contract Manufacturer
D223316	K111187		DXZ	PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE	Contract Manufacturer
D289980	K161762		NPL	Barrier, animal source, intraoral	Manufacturer
D223317	K140789		DXZ	PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE	Contract Manufacturer
D289982	K162741		JXI	CUFF, NERVE	Manufacturer
D131547	K110402		FTM	Mesh, surgical	Manufacturer
D423700	K160136		KGN	Wound dressing with animal-derived material(s)	Manufacturer
D268397	K161221		FTM	Mesh, surgical	Manufacturer
D298936	K170016		FTM	Mesh, surgical	Manufacturer
D023630	K031069		JXI	CUFF, NERVE	Manufacturer
D303408	K053622		NXM	Prosthesis, eyelid spacer/graft, biologic	Contract Manufacturer
D021575	K062320		FTM	Mesh, surgical	Manufacturer
D021569	K992159		PAG	mesh, surgical, non-synthetic, urogynecologic, for stress urinary incontinence, retropubic or transobturator	Manufacturer
			PAJ	Mesh, surgical, non-synthetic, urogynecologic, for apical vaginal and uterine prolapse, transabdominally placed	
			FTM	Mesh, surgical	

D023626	K050337		FTM	Mesh, surgical	Manufacturer
D407845	K191696		OXN	Mesh, surgical, collagen, fistula	Manufacturer
			FTM	Mesh, surgical	
			OXH	Mesh, surgical, collagen, plastic and reconstructive surgery	
D187330	K121360		KHJ	POLYMER, ENT SYNTHETIC-POLYAMIDE (MESH OR FOIL MATERIAL)	Manufacturer
D023585	K062697		FTL	Mesh, surgical, polymeric	Manufacturer
D023622	K062729		FTM	Mesh, surgical	Manufacturer
D303753	K163446		JXI	CUFF, NERVE	Contract Manufacturer
D021564	K020654		PAG	mesh, surgical, non-synthetic, urogynecologic, for stress urinary incontinence, retropubic or transobturator	Manufacturer
D062220	K082058		NPL	Barrier, animal source, intraoral	Manufacturer
D515500	K223640		JXI	CUFF, NERVE	Contract Manufacturer
D222370	K133306		OXK	Mesh, surgical, collagen, large abdominal wall defects	Manufacturer
			FTM	Mesh, surgical	
D023569	K031850		GXQ	DURA SUBSTITUTE	Manufacturer
D021549	K061711		KGN	Wound dressing with animal-derived material(s)	Manufacturer
D203358	K131015		GXQ	DURA SUBSTITUTE	Manufacturer

