August 6, 2025

Integra LifeSciences Production Corporation
Kali Sacco
Manager, Regulatory Affairs
11 Cabot Boulevard
Mansfield, Massachusetts 02048

Re: K243552
Trade/Device Name: Codman Libertís™ 1.5 mm EVD Catheter with Bactiseal® and Endexo® Technology with Luer Connection (821761); Codman Libertís™ 1.9 mm EVD Catheter with Bactiseal® and Endexo® Technology with Luer Connection (821762)
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: Class II
Product Code: JXG
Dated: November 15, 2024
Received: July 7, 2025

Dear Kali Sacco:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yen-chih Lin -S

Digitally signed by Yen-chih Lin -S
Date: 2025.08.06 16:51:02 -04'00'

For
Adam Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243552

Device Name

Codman Libertís™ 1.5 mm EVD Catheter with Bactiseal® and Endexo® Technology with Luer Connection (821761);
Codman Libertís™ 1.9 mm EVD Catheter with Bactiseal® and Endexo® Technology with Luer Connection (821762)

Indications for Use *(Describe)*

The Codman Libertís™ EVD Catheter with Bactiseal® and Endexo® Technology is indicated for gaining access to the ventricles of the brain and can be used with dimensionally compatible devices for draining cerebrospinal fluid (CSF) and other fluids of similar physical characteristics as a means of reducing intracranial pressure and CSF volume.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a) (1) Submitter Information	
Name and Address	Integra LifeSciences Production Corporation 11 Cabot Boulevard Mansfield, MA 02048
Telephone number	(680) 910-4999
Primary Contact	Kali Sacco
Date Summary Prepared	August 6, 2025
807.92(a) (2) Name of Device	
Trade or Proprietary Name	Codman Libertís™ EVD Catheter with Bactiseal® and Endexo® Technology
Common Name	Ventricular Catheters
Classification Name	Central Nervous System Fluid Shunt and Components (21 CFR 882.5550)
Device Class	II
Product Code	JXG
807.92(a) (3) Predicate Information	
Predicate Device	Bactiseal EVD Catheter Sets and Bactiseal Clear EVD Catheter Set (K233448)
807.92(a) (4) Device Description	
The Codman Libertís™ EVD Catheter with Bactiseal® and Endexo® Technology (Libertís™ EVD Catheters) include a ventricular catheter that is supplied with component accessories that facilitate placement and use of the catheter for reducing and controlling intracranial pressure due to excess cerebrospinal fluid (CSF). The ventricular catheter is subjected to a treatment process by which the silicone is impregnated with two antimicrobials, rifampicin and clindamycin hydrochloride. Laboratory studies show Bactiseal treated catheters reduce the colonization of gram-positive bacteria on the tubing surface. Additionally, Libertís™ EVD Catheters contain an Endexo® polymer additive; a surface modifying macromolecule (SMM) polymer blended into the catheter's base silicone. The ventricular catheter is placed in the ventricles of the brain and CSF enters the fluid conduit through the inlet holes near the tip of the catheter and drains into the external drainage system connected to the catheter. The catheter contains a barium sulfate stripe for radiopacity and includes numerical depth markings and circumferential bands, made of ink, from the proximal tip.	
807.92(a) (5) Indications for Use	
The Codman® Libertís™ EVD Catheter with Bactiseal® and Endexo® Technology is indicated for gaining access to the ventricles of the brain and can be used with dimensionally compatible devices for draining cerebrospinal fluid (CSF) and other fluids of similar physical characteristics as a means of reducing intracranial pressure and CSF volume.	
807.92(a) (6) Technological Characteristics Compared to Predicate	
The proposed Libertís™ EVD Catheters have the same intended use and functionality as the predicate devices. The proposed changes to the design, materials, and sterility do not raise different questions of safety and/or effectiveness.	

Component Affected	Proposed Modification	Rationale
Libertís™ EVD Catheters	Addition of Endexo additive	A surface modifying macromolecule (SMM) polymer blended into the catheter's base silicone. The Endexo technology modifies polymeric medical device surfaces to passively reduce the protein – biomaterial interactions which mediate thrombus formation and cellular adhesion.
	The diameter of the catheter inlet hole on the smaller diameter catheter (821761) is larger than the predicate P/N 821745 and there are fewer inlet holes	To ensure the same performance specifications as the predicate by maintaining the same inlet hole opening surface area.
	Additional ventricular catheter markings	Addition of numerical markings and circumferential bands is part of continuous improvement in catheter usability
	Different material formulations in the ink markings	A different ink formulation was used to ensure adherence to the catheter.
Catheter Anchoring Clip	Different material formulation	To accommodate the manufacturing processes
	Increased thickness of the catheter anchoring clip	Continuous improvement for usability
Trocar	Reduced diameter in the bending region	More bendable as part of continuous improvement
	Reduced barb ridges to 4 compared to 6 on the predicate	Continuous improvement for usability to maintain consistency between the trocars used with each Libertís EVD Catheter (821761 and 821762)
Stylet for 821761	Decreased cross-section size of the stylet	The decrease in cross-section is required due to the smaller size of the catheter
Catheter and Stylet	Sterilization using electron-beam radiation	Radiation (electron beam) sterilization methods were chosen to reduce thermal degradation of the antibiotics.
Packaging of Catheter and Stylet	Change the catheter and stylet tray to PETG	PETG was selected for greater compatibility with electron beam sterilization
	Change the sterile barrier for the proposed catheter and stylet to two sheets of nylon/LDPE (low density polyethylene) rather than Tyvek 1073B and polyester/polyolefin.	To facilitate packaging in a low pressure N_2 atmosphere.
	Filling the pouch with low pressure N_2	To reduce oxidative degradation of the antibiotics
Labeling	Device and package labels: • New device name • New reference number (SKU) • New description to identify contents of each pouch • Updated symbology for pouch containing Catheter and Stylet	To accurately reflect Libertís EVD Catheter

	to identify the sterilization method	
Instructions for Use	• Update Description to add information about Endexo and location of catheter marking and inlet holes • Revised How Supplied section to describe the two separate sterilized pouches and contents • Added symbol for sterilization method change	Technological differences between the Libertís EVD Catheter and predicate Codman Bactiseal EVD Catheters (K233448)
	Added new sections: Intended Clinical Benefits, Intended User, Intended Patient Population, Disposal	To align with EU regulatory labeling requirements
	Added statement that the trocar and stylet provided to aid in the placement of the Codman Libertís EVD Catheter are MR-Unsafe	The trocar and stylet are not intended to be used in the MR environment and are labeled MR-unsafe

807.92(b) 1-2: Summary of Nonclinical and Clinical Testing Performed

The following performance testing has been conducted in support of the substantial equivalence determination. The testing utilized FDA recognized consensus standards and internal test methods. All testing was performed on production equivalent devices.

Performance Bench Test Results	
Test	**Conclusion**
Evaluation of Codman Libertís EVD Catheters per ASTM F647 and ISO 7197	Pass
Evaluation of Aged Codman Libertís EVD Catheters per ASTM F647 and ISO 7197 (T = 12 months)	Pass
Functional/Mechanical Performance of Codman Libertís EVD Catheters	Pass
Functional/Mechanical Performance of Aged Codman Libertís EVD Catheters (T = 12 months)	Pass
MRI Compatibility Assessment of Codman Libertís EVD Catheters per ASTM F2503	Pass
Antimicrobial Efficacy of Codman Libertís EVD Catheters – Zone of Inhibition (ZOI) after 28 Days of Simulated Use	Pass
Antimicrobial Efficacy of Aged Codman Libertís EVD Catheters – Zone of Inhibition (ZOI) after 28 Days of Simulated Use (T = 12 months)	Pass
Antibiotic Content Testing of Codman Libertís EVD Catheters	Pass
Residual Solvents Testing of Codman Libertís EVD Catheters	Pass

Libertís EVD Catheters with Bactiseal® and Endexo® Technology – Summative Usability Study	Pass
Product Shelf Life Testing per ASTM F1980 and ISO 11607-1	Pass

Biocompatibility Testing Results	
Test	**Conclusion**
Biocompatibility Testing per ISO 10993-1	Pass

Sterilization/Cleaning

The proposed device (Codman Libertís™ EVD Catheter and stylet) is sterilized via electron beam radiation. A sterilization validation was performed and determined that the sterility assurance level achieved (SAL = 10^{-6}) is equivalent to the sterility level achieved in the predicate device, which is sterilized via steam. There has been no change to the sterilization method (steam sterilized) or sterility assurance level (SAL = 10^{-6}) for the Libertís™ EVD Catheter accessories (Trocar, Female LUER-LOK™ Connectors, Male LUER-LOK Cap, and Catheter Anchoring Clip) as compared to the predicate device.

Shelf Life

There are no changes in shelf life as a result of the proposed changes. The proposed device, Codman Libertís™ EVD Catheter with Bactiseal® and Endexo® Technology shelf life is 12 months which is the same as the predicate.

Animal Studies

No animal studies were required as appropriate verification and validation testing of the subject device was achieved based on the comparison to the predicate device and from the results of the bench testing.

Clinical Studies

No clinical studies were required as appropriate verification and validation testing of the subject device was achieved based on the comparison to the predicate device and from the results of the bench testing.

807.92(b) (3) Conclusion

Based upon the intended use, design, comparison to the predicate device, and testing performed, Integra LifeSciences believes that the proposed modifications to the Codman Libertís™ EVD Catheter with Bactiseal® and Endexo® Technology do not raise different questions of safety and effectiveness, and is therefore, substantially equivalent to the predicate Bactiseal EVD Catheter Sets and Bactiseal Clear EVD Catheter Set.