August 8, 2025

Integra LifeSciences Production Corporation
David Arroyo
Sr. Regulatory Affairs Specialist
11 Cabot Boulevard
Mansfield, Massachusetts 02048

Re: K243531
Trade/Device Name: Codman Libertís Shunt Catheter with Bactiseal and Endexo Technology
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt And Components
Regulatory Class: Class II
Product Code: JXG
Dated: November 14, 2024
Received: July 11, 2025

Dear David Arroyo:

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: 2025.08.08 17:44:25 -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)*

K243531

Device Name

Codman Libertís Shunt Catheter with Bactiseal and Endexo Technology

Indications for Use *(Describe)*

For use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid (CSF) is indicated.

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.

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	(609) 627-9053
Primary Contact	David A. Arroyo
Date Summary Prepared	August 8, 2025
807.92(a) (2) Name of Device	
Trade or Proprietary Name	Codman® Libertís™ Shunt Catheter with Bactiseal® and Endexo® Technology
Common Name	Hydrocephalus Shunt System Hydrocephalus Catheters
Classification Name	Shunt, Central Nervous System and Components (21 CFR 882.5550)
Device Class	II
Product Code	JXG
807.92(a) (3) Predicate Information	
Predicate Device	Codman® Bactiseal® Shunt Catheter: K233445
807.92(a) (4) Device Description	
The Libertís™ Shunt Catheter includes a ventricular and distal (peritoneal) drainage catheter that are used as part of a cerebrospinal fluid (CSF) shunting system to treat hydrocephalus. Both catheters are attached to the valve portion of a shunting system. The ventricular catheter diverts excess CSF from the ventricles of the brain through the valve. After passing through the valve, the excess CSF is drained through the distal catheter into another part of the body, such as the peritoneal cavity, where it is reabsorbed into the bloodstream. The catheters have Endexo® polymer, a surface modifying macromolecule, blended into their base silicone. The catheters are subjected to a treatment process by which the silicone is impregnated with two antimicrobials, rifampicin and clindamycin hydrochloride. The Libertís™ Shunt Catheter has been shown in laboratory studies to reduce the colonization of gram-positive bacteria on the tubing surface. The catheters contain barium sulfate for radiopacity and have ink markings on the silicone tubing to aid in positioning of the catheter. The catheters are packaged with two accessories, a stylet and a right-angle adapter. The stylet is used to help introduce the ventricular catheter into the brain's ventricles. The right-angle adapter is used to fixate the ventricular catheter to the cranium.	
807.92(a) (5) Indications for Use	
For use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid (CSF) is indicated.	
807.92(a) (6) Technological Characteristics Compared to Predicate	
The Libertís™ Shunt Catheter has the same intended use, same functionality, same antibiotics, same radiopaque material, and similar design specifications as the predicate device. Compared to the predicate, the proposed device adds a new material, Endexo®, is made of an equivalent silicone, has markings made of ink instead of tantalum, offers a new length of ventricular catheter and stylet, and uses different packaging materials. The differences in technological characteristics do not raise different questions of safety and effectiveness, compared to the predicate.	

Component Affected	Proposed Modification	Rationale
Catheters Materials	The proposed device and the predicate device are made of base silicones from different manufacturers. Addition of Endexo® additive to the base silicone in the proposed device.	The proposed device is made of implant-grade platinum-cured silicone, equivalent to that of the predicate. Endexo® is a surface modifying macromolecule (SMM) polymer blended into the catheter's base silicone.
Ventricular Catheter Markings	The proposed device's markings consist of numbers with circumferential bands, which are made of implant-grade ink and silicone adhesive. The predicate device's markings consist of tantalum dots. The proposed device also has additional markings compared to the predicate device.	The addition of numerical markings and circumferential bands is part of continuous improvement in catheter usability.
Ventricular Catheter Length	The proposed device's ventricular catheter comes in 14 cm and 23 cm lengths. In comparison, the predicate device's ventricular catheter only has a 14 cm option.	Adding a 23 cm ventricular catheter supports the variety of approaches and valve placements used in hydrocephalus shunting.
Ventricular Catheter Inlet Holes	The proposed device has a smaller number of inlet holes, compared to the predicate devices. The inlet holes in the proposed device are of different size and shape, and have a different spatial arrangement, compared to the predicate.	The change in the number, size, shape, and spatial arrangement of the inlet holes is part of continuous improvement in catheter usability.
Stylet	The stylets of the proposed device have a square shaped cross section, compared to a circular shape in the proposed device's stylet. A longer stylet is paired with the longer ventricular catheter (23 cm).	The square shaped cross section of the stylet is part of continuous improvement in catheter usability. The longer stylet is required for aiding the insertion of the new 23 cm ventricular catheter.
Ventricular and Distal Catheters Radiopacity	Both the proposed and predicate devices use barium sulfate for radiopacity. The proposed ventricular and distal catheters are translucent with a radiopaque stripe along the entire length of the catheter	The use of a barium sulfate stripe in a translucent catheter is part of continuous improvement in catheter usability.

	tubing. In comparison, the predicate device is fully radiopaque.	
Packaging	The predicate and the proposed devices use a double sterile barrier system composed of a sealed tray/lid system inside a sealed pouch. Some of the components of the packaging systems are made with different materials.	The differences in packaging materials are intended to support sterilization and to reduce degradation of the antibiotics in the catheters.

In addition to the differences in the materials and design of the proposed and the predicate devices, the devices are sterilized using different methods and have different MRI compatibility. The proposed device is sterilized using E-beam radiation while the predicate is sterilized using steam. Both sterilization methods achieve the same Sterility Assurance Level (SAL = 10^{-6}). The proposed device has an MR-safe designation while the predicate has an MR-conditional designation. The difference in MRI compatibility is due to the absence of tantalum, a metallic alloy, in the markings of proposed device.

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 was performed according to FDA-recognized consensus standards and internal test methods. All testing was performed on production equivalent devices.

Performance Bench Test Results	
Test	**Conclusion**
Evaluation of Safety and Performance per ISO 7197 and ASTM F647-94	Pass
Functional/Mechanical Performance per ASTM F647-94 and ASTM D412-16	Pass
MRI Compatibility per ASTM F2053-20	Pass
Antimicrobial Efficacy – Zone of Inhibition (ZOI) per internal methods	Pass
Antibiotic Content Analysis using High-performance Liquid Chromatography (HPLC), per internal methods	Pass
Residual Solvents Testing via Headspace Gas Chromatography – Flame Ionization Detection (HS GC-FID), per FDA guidance "Q3C – Tables and List Guidance for Industry	Pass
Usability Evaluation and Design Validation per IEC 62366-1	Pass
In vitro flow loop thrombogenicity test	Observed significantly less thrombus deposition on Codman Libertis Distal Shunt Catheter with Bactiseal and Endexo Technology compared to predicate device

Biocompatibility Testing Results	
Test	**Conclusion**
Cytotoxicity per ISO 10993-5:2009	Pass
Sensitization per ISO 10993-10:2021	Pass
Irritation per ISO 10993-10:2021 and ISO 10993-23:2021	Pass
Acute Systemic Toxicity per ISO 10993-11:2017	Pass
Pyrogenicity per ISO 10993-11:2017	Pass
Subacute/Subchronic Toxicity per ISO 10993-6:2016 and ISO 10993-11:2017	Pass
Genotoxicity per ISO 10993-3:2014	Pass
Implantation per ISO 10993-6:2016	Pass
Chronic Toxicity per ISO 10993-11:2017	Pass
Hemocompatibility per ISO 10993-4:2017	Pass
Carcinogenicity per ISO 10993-3:2014	Pass

Sterilization/Cleaning
The proposed device is sterilized via electron beam (E-beam) radiation. A sterilization validation was performed according to FDA recognized standards ISO 11137-1, ISO 11137-2, ISO 11737-1, and ISO 11737-2. The sterilization validation demonstrates that the proposed sterilization method achieves a sterility assurance level (SAL) of 10^{-6}.

Shelf Life
The shelf-life established for the predicate and the proposed devices is the same, 1-year.

Clinical Studies
No clinical studies were required as appropriate verification of the subject devices was achieved based on the comparison to the predicate devices 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 Libertís™ Shunt Catheter does not raise any different questions of safety and effectiveness, and is therefore, substantially equivalent to the predicate Bactiseal® Shunt Catheter.