June 23, 2026

Integra Lifesciences Production Corporation
Leigh Anne Diener
Regulatory Specialist
11 Cabot Blvd.
Mansfield, Massachusetts 02048

Re: K261004
Trade/Device Name: Codman® Distal Peritoneal Catheter, Barium Open End (82-1682);
Codman® HOLTER® Peritoneal Catheter (SALMON Design) (82-1684)
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt And Components
Regulatory Class: Class II
Product Code: JXG
Dated: March 26, 2026
Received: March 26, 2026

Dear Leigh Anne Diener:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.06.23 15:44:13 -04'00'

for Jaime Raben, Ph.D.,
Division 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261004

Please provide the device trade name(s).

Codman® Distal Peritoneal Catheter, Barium Open End (82-1682);
Codman® HOLTER® Peritoneal Catheter (SALMON Design) (82-1684)

Please provide your Indications for Use below.

Codman® Distal Peritoneal Catheter, Barium Open End is indicated for use with a proximal valve in the treatment of hydrocephalus where ventriculoperitoneal shunting is the procedure of choice.

The HOLTER Peritoneal Catheter (SALMON Design) is indicated for use with a HOLTER Valve in the treatment of hydrocephalus where the ventriculoperitoneal shunting technique is the procedure of choice.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☐ Adults (22 years old and greater)

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	+1 781-971-5601
Primary Contact	Leigh Anne Diener
Date Summary Prepared	January 28, 2026
807.92(a) (2) Name of Device	
Trade or Proprietary Name	Codman® Distal Peritoneal Catheter, Barium Open End Codman® HOLTER® Peritoneal Catheter (SALMON Design)
Common Name	Hydrocephalus Shunt System
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	Codman® Distal Peritoneal Catheter, Barium Open End - Preamendment Codman® HOLTER® Peritoneal Catheter (SALMON Design) - Preamendment
807.92(a) (4) Device Description	
The Codman® Distal Peritoneal Catheter, Barium Open End and Codman® HOLTER® Peritoneal Catheter (SALMON Design) are sterile, single use, peritoneal drainage catheters that are used as part of a CSF shunting system to treat hydrocephalus. Both types of catheters may be attached to the distal end of a valve shunting system and the distal end of the catheter is then implanted into the Peritoneal cavity of the patient. The excessive CSF which is regulated by the valve is then drained through the peritoneal drainage catheter into the peritoneal cavity where it is reabsorbed into the bloodstream. The Codman® Distal Peritoneal Catheter, Barium Open End and Codman® HOLTER® Peritoneal Catheter (SALMON Design) are made of radiopaque silicone tubing.	
807.92(a) (5) Indications for Use	
Codman® Distal Peritoneal Catheter, Barium Open End is indicated for use with a proximal valve in the treatment of hydrocephalus where ventriculoperitoneal shunting is the procedure of choice. The HOLTER Peritoneal Catheter (SALMON Design) is indicated for use with a HOLTER Valve in the treatment of hydrocephalus where the ventriculoperitoneal shunting technique is the procedure of choice.	
807.92(a) (6) Technological Characteristics Compared to Predicate	
The proposed Codman® Distal Peritoneal Catheter, Barium Open End and Codman® HOLTER® Peritoneal Catheter (SALMON Design) have the same intended use, design, materials, sterility, and principles of operation as the predicate devices. The proposed changes to labeling do not impact the technological characteristics of the devices. The changes do not raise any new questions of safety and effectiveness.	

Document, Section (if applicable)	Update	Rationale
IFU, Throughout Document	Formatting, clerical changes, and addition of new sections.	Proposed updates drive additional consistency across and within global product IFUs and in support of EU Medical Device Regulation compliance.
IFU and Labeling, Magnetic Resonance Imaging (MRI) Safety Information	MRI safety information added and include an "MR Conditional" claim.	Testing provided in submission to support an "MR Conditional" claim for the catheters.
IFU, Patient Implant Card, and Patient Information Leaflet	Addition of instructions for healthcare describing how to complete the card and additional information on the card and leaflet that should be advised to the patient. PIC and PIL are new documents provided to customer in packaging.	Patient Implant Card and Patient Information Leaflet are to be provided to patient per FDA guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*, issued on October 10, 2023, as the catheters are MR conditional devices.
IFU and Labeling, Symbols	Symbols have been updated to include harmonized symbols per ISO 15223-1.	Symbols now align with the latest version of ISO 15223-1.

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 well-established methods, including those from FDA consensus standards. All testing was performed on production equivalent devices.

Performance Bench Test Results	
Test	**Conclusion**
MRI Safety Testing per ASTM F2052, ASTM F2213, ASTM F2182 and ASTM FF2119	Pass

Sterilization/Cleaning

There are no changes in sterility as a result of the proposed changes.

Shelf Life

There are no changes in shelf life as a result of the proposed changes.

Animal Studies

No animal 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 and analysis.

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 and analysis.

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® Distal Peritoneal Catheter, Barium Open End and Codman® HOLTER® Peritoneal Catheter (SALMON Design) do not raise any new questions of safety and effectiveness, and is therefore, substantially equivalent to the predicate Codman® Distal Peritoneal Catheter, Barium Open End and Codman® HOLTER® Peritoneal Catheter (SALMON Design).