January 17, 2024

Integra LifeSciences Production Corporation
Jocelyn Raposo
Director, Regulatory Affairs
11 Cabot Boulevard
Mansfield, Massachusetts 02048

Re: K233445
Trade/Device Name: Bactiseal Catheters
Bactiseal Barium Striped Catheters
Bactiseal Endoscopic Ventricular Catheter
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt And Components
Regulatory Class: Class II
Product Code: JXG, HCA
Dated: October 19, 2023
Received: October 19, 2023

Dear Jocelyn Raposo:

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.

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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2024.01.17 16:07:40 -05'00'

Adam D. 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233445

Device Name

Bactiseal Catheters;
Bactiseal Barium Striped Catheters;
Bactiseal Endoscopic Ventricular Catheter

Indications for Use *(Describe)*

The Bactiseal Catheters are indicated for use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid (CSF) is indicated.

The Bactiseal Barium Striped Catheters are indicated for use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid (CSF) is indicated.

The Bactiseal Endoscopic Ventricular Catheter is designed for use in the treatment of hydrocephalus when shunting cerebrospinal fluid (CSF) from the ventricles of the brain.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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	Amanda Erwin
Date Summary Prepared	January 2, 2024
807.92(a) (2) Name of Device	
Trade or Proprietary Name	Bactiseal Catheters Bactiseal Barium Striped Catheters Bactiseal Endoscopic Ventricular Catheter
Common Name	Hydrocephalus Shunt System Hydrocephalus Catheters
Classification Name	Central Nervous System Fluid Shunt and Components (21 CFR 882.5550) Ventricular Catheter (21 CFR 882.4100)
Device Class	II
Product Code	JXG, HCA
807.92(a) (3) Predicate Information	
Predicate Device	Bactiseal Catheters: K172022 Bactiseal Barium Striped Catheters: K031123 Bactiseal Endoscopic Ventricular Catheter: K110751
807.92(a) (4) Device Description	
The Bactiseal Catheters, Bactiseal Barium Striped Catheters and Bactiseal Endoscopic Ventricular Catheter include a ventricular and/or distal (peritoneal) drainage catheter that are used as part of a CSF shunting system to treat hydrocephalus. Both catheters are attached to the valve portion of a shunting system, which is then implanted in the patient's brain. The ventricular catheter diverts the excessive CSF from the ventricles of the brain through the valve. After passing through the valve, the excessive CSF is drained through the distal (peritoneal) drainage catheter into another part of the body, such as the peritoneal cavity, where it is reabsorbed into the bloodstream. The catheters are subjected to a treatment process by which the silicone is impregnated with two antimicrobials, rifampicin and clindamycin hydrochloride. Bactiseal silicone catheters have 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 tantalum "dots" incorporated onto the silicone tubing to aid in positioning of the catheter. The Bactiseal Catheters and Bactiseal Endoscopic Ventricular Catheter are made of radiopaque silicone tubing, and the Bactiseal Barium Striped Catheters are made of clear silicone tubing with radiopaque striping. The Bactiseal Endoscopic Ventricular Catheter has a slit in the tip of the ventricular catheter in order for the catheter to be placed with the use of an endoscope.	
807.92(a) (5) Indications for Use	
The Bactiseal Catheters and Bactiseal Barium Striped Catheters are indicated for use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid is indicated.	

The Bactiseal Endoscopic Ventricular Catheter is designed for use in the treatment of hydrocephalus when shunting cerebrospinal fluid (CSF) from the ventricles of the brain.

807.92(a) (6) Technological Characteristics Compared to Predicate

The proposed Bactiseal Catheters, Bactiseal Barium Striped Catheters and Bactiseal Endoscopic Ventricular Catheter have the same intended use, design, materials, sterility, and fundamental operation as the predicate devices. The proposed changes to labeling and the supplier of the clindamycin hydrochloride do not impact the technological characteristics of the devices. The changes do not raise any new questions of safety and/or effectiveness.

Component Affected	Proposed Modification	Rationale
Labeling	• MRI labeling changes: Bactiseal Endoscopic Ventricular Catheter: Updated MR labeling from MR Safe to MR Conditional Bactiseal Barium Striped Catheters: MR Conditional labeling claim added and clarification that this claim only applies to the catheters and right angle adapter Bactiseal Catheters: Updated MR labeling to clarify that only the catheters and right angle adapter are MR Conditional	• MRI labeling changes: Bactiseal Endoscopic Ventricular Catheter: the labeling is being updated for consistency with other Bactiseal catheters that contain tantalum. Bactiseal Barium Striped Catheters: The labeling is being updated for consistency with other Bactiseal catheters that contain tantalum. The catheters are packaged with accessories, including a stylet. Since the stylet is only used during the catheter implant procedure, it is not intended to go into an MR environment. Therefore, the labeling will clarify that only the catheter and right angle adapter are MR Conditional. Bactiseal Catheters: The catheters are packaged with accessories, including a stylet. Since the stylet is only used during the catheter implant

		procedure, it is not intended to go into an MR environment. Therefore, the labeling will clarify that only the catheter and right angle adapter are MR Conditional.
	• Inclusion of a Patient Implant Card and a Patient Information Leaflet	• A Patient Implant Card is required per FDA's current guidance, *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*, issued on October 10, 2023. The patient information leaflet is provided as it includes information essential for understanding the information included on the patient implant card and additional information on the device itself that cannot be provided directly on the patient implant card due to space availability.
	• Made administrative updates and updates to harmonized symbols per ISO 15223-1.	• Administrative updates and compliance with the latest standard.
Bactiseal Catheter Silicone Tubing	Integra is proposing a new supplier for clindamycin hydrochloride. The clindamycin hydrochloride is impregnated into the Bactiseal catheter silicone tubing.	Integra has made the decision to change the supplier for the clindamycin hydrochloride. Testing has been executed to confirm that the clindamycin hydrochloride from the new supplier is considered equivalent to the clindamycin hydrochloride from the current supplier based on material specification and drug efficacy requirements. This testing

		verified that the new source does not raise any questions of safety and effectiveness and supports that the new source is equivalent to the clindamycin hydrochloride used in the predicate devices as it has the same characterizations based on identity, formulation, concentration of the antimicrobial agent, method of application to the device, mechanism of drug release and continues to meet the same drug specifications. A Biocompatibility Assessment was performed which determined that the introduction of the new supplier for clindamycin hydrochloride does not introduce any new issues related to biocompatibility and additional testing would not be necessary.

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
Drug Equivalency Testing per USP standards and USP Monograph for Clindamycin Hydrochloride	Pass
Drug Effectiveness Testing per USP <81> and internal test methods.	Pass

Sterilization/Cleaning

There are no changes in sterility as a result of the proposed changes. A sterilization equivalency assessment was performed comparing the predicate devices to the proposed device, using clindamycin hydrochloride from the new supplier, and the results were deemed acceptable.

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 engineering 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 engineering 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 Bactiseal Catheters, Bactiseal Barium Striped Catheters and Bactiseal Endoscopic Ventricular Catheter do not raise any new questions of safety and effectiveness, and is therefore, substantially equivalent to the predicate Bactiseal Catheters, Bactiseal Barium Striped Catheters and Bactiseal Endoscopic Ventricular Catheter.