December 19, 2023

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

Re: K233448
Trade/Device Name: Bactiseal EVD Catheter Sets, Bactiseal Clear EVD Catheter Set
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt And Components
Regulatory Class: Class II
Product Code: JXG
Dated: October 19, 2023
Received: October 20, 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: 2023.12.19 18:01:40 -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)*

K233448

Device Name

Bactiseal EVD Catheter Sets;
Bactiseal Clear EVD Catheter Set

Indications for Use *(Describe)*

The Bactiseal EVD Catheter and Bactiseal Clear EVD Catheter sets are 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.

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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	(609) 627-9053
Primary Contact	Amanda Erwin
Date Summary Prepared	October 27, 2023
807.92(a) (2) Name of Device	
Trade or Proprietary Name	Bactiseal EVD Catheter Sets Bactiseal Clear EVD Catheter Set
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 Set: K021653 Bactiseal EVD Catheter Set and Bactiseal Clear EVD Catheter Set: K090348

807.92(a) (4) Device Description

The Bactiseal EVD Catheter Sets and Bactiseal Clear EVD Catheter Set 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. 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. 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 barium sulfate 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 Bactiseal EVD Catheter Sets and Bactiseal Clear EVD Catheter Set are 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 Bactiseal EVD Catheter Sets and Bactiseal Clear EVD Catheter Set 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: an update will be made	• The catheter, LUER-LOK connector and cap

	to state that the catheter, LUER-LOK connector and cap and anchoring clip are MR Safe. • Administrative updates and updates to harmonized symbols per ISO 15223-1.	and anchoring clip are MR Safe devices and labeling has been updated to reflect this information. • 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 source 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. All testing was performed on production equivalent devices.

Performance Bench Test Results	
Test	**Conclusion**
Drug Equivalency Testing per USP standards and USP Monograph for clindamycin hydrochloride	Pass
Drug Effectiveness Testing per USP <81> and internal test method.	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 device 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 EVD Catheter Sets and Bactiseal Clear EVD Catheter Set do not raise any new questions of safety and effectiveness, and is therefore, substantially equivalent to the predicate Bactiseal EVD Catheter Sets and Bactiseal Clear EVD Catheter Set.