October 16, 2017

Codman & Shurtleff, Inc.
Christopher Garete
Regulatory Affairs Specialist II
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K172537
Trade/Device Name: CODMAN EDS 3 CSF External Drainage System; External Drainage System Collection Bag
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: August 21, 2017
Received: August 22, 2017

Dear Mr. Christopher Garete:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172537

Device Name
CODMAN EDS 3 CSF External Drainage System
External Drainage System Collection Bag

Indications for Use *(Describe)*
Use of the CODMAN EDS 3 CSF External Drainage System (EDS 3) is indicated for draining cerebrospinal fluid (CSF) from the cerebral ventricles or the lumbar subarachnoid space as a means of reducing intracranial pressure and CSF volume when the insertion of a permanent, internal shunt is not indicated.

Use the External Drainage System Collection Bag with the CODMAN EDS 3 External Drainage System to measure and collect cerebrospinal fluid (CSF).

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.

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K172537 – 510(k) Summary

I. Submitter

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767

Establishment Registration Number: 1226348

Primary Contact: Christopher Garete
Phone: (508) 977-3869
Fax: (508) 977-6979

Secondary Contact: Megan Palumbo
Phone: (508) 828-3571
Fax: (508) 977-6979

Date of Preparation: August 21, 2017

II. Device

Device Proprietary Name	CODMAN EDS 3 CSF External Drainage System External Drainage System Collection Bag
Common Name	External Drainage System
Classification Name	Central Nervous System Fluid Shunt and Components (21 CFR 882.5550)
Regulatory Classification	II
Product Code	JXG

III. Predicate Device

The predicate device for this submission is:

Codman EDS 3 CSF External Drainage System (K162437), which was cleared on October 28, 2016.

IV. Device Description

The Codman EDS 3 CSF External Drainage System (Codman EDS 3 System) is designed to drain cerebral spinal fluid (CSF) at a controlled rate based on differential pressure between the device and the patient. Collecting CSF from the patient is performed in efforts to reduce elevated intracranial pressure (ICP) post trauma. The EDS 3 device is comprised of four (4) main parts: ventricular catheter, patient drain line, base frame drip chamber assembly, and a collection bag. Note: The collection bag is sold as part of the Codman EDS 3 System, as well as sold separately.

The principle of operation of the proposed Codman EDS 3 system is identical to the currently marketed Codman EDS 3 system. The ventricular catheter is placed into one of the ventricles in the brain or in the subarachnoid space and is then connected to the patient drainage line. CSF flows from the brain or lumbar region through the patient line and enters into the 100 mL graduated drip chamber assembly, where it is collected

over a period of time to calculate a flow rate. The drip chamber assembly can then be raised or lowered along the base frame, thereby adjusting the differential pressure to achieve the appropriate flow rate. Once the drip chamber height is set, the collected CSF is then drained into the attached 700 mL collection bag.

The Codman EDS 3 CSF External Drainage System Collection Bag is a sterile, vented 700 mL capacity bag that is graduated in 50 mL increments for accurate measurement. A microbial-retentive atmospheric vent facilitates CSF flow into the bag. One bag is provided with the system and replacement bags are sold separately as an accessory to the drain.

The EDS 3 system is a complete, disposable unit that is provided sterile and is available with or without a ventricular catheter.

V. Indications for Use

The Indications for Use statement of the proposed devices remain identical to those of the predicate devices.

Equivalence Comparison	Codman EDS 3 CSF External Drainage System (Predicate: K162437)	Codman EDS 3 CSF External Drainage System (Subject of This Submission)
EDS 3 System Indications for Use	Use of the CODMAN EDS 3 CSF External Drainage System (EDS 3) is indicated for draining cerebrospinal fluid (CSF) from the cerebral ventricles or the lumbar subarachnoid space as a means of reducing intracranial pressure and CSF volume when the insertion of a permanent, internal shunt is not indicated. Use the External Drainage System Collection Bag with the CODMAN EDS 3 External Drainage System to measure and collect cerebrospinal fluid (CSF).	Same as predicate

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VI. Comparison to Predicate Device

The proposed Codman EDS 3 CSF External Drainage System is identical to the currently marketed Codman EDS 3 CSF External Drainage System (K162437) except for the following changes proposed in this submission:

- a new filter membrane material in the burette cap
- a wider pole clamp design with a shorter thumb screw
- a straightened and wider diameter base frame tube
- a new collection bag design

The indications for use, principle of operation, clinical utility, packaging, and sterilization remain identical to the predicate devices. The proposed design is similar to that of the predicate device.

Substantial Equivalence Comparison		
Characteristic	**Codman EDS 3 CSF External Drainage System and Bags (Predicate: K162347)**	**Codman EDS 3 CSF External Drainage System and Bags (Subject of This Submission)**
Manufacturer	Codman & Shurtleff, Inc.	Same as predicate
Classification Panel	Neurology	Same as predicate
Classification Name	Central Nervous System Fluid Shunt and Components (21 CFR 882.5550)	Same as predicate
Indications for Use	Use of the CODMAN EDS 3 CSF External Drainage System (EDS 3) is indicated for draining cerebrospinal fluid (CSF) from the cerebral ventricles or the lumbar subarachnoid space as a means of reducing intracranial pressure and CSF volume when the insertion of a permanent, internal shunt is not indicated. Use the External Drainage System Collection Bag with the CODMAN EDS 3 External Drainage System to measure and collect cerebrospinal fluid (CSF).	Same as predicates
Operating Principle	Drainage of CSF based on a differential pressure between the patient and the device.	Same as predicate
Single Use Only	Yes	Same as predicate
Shelf Life	3 years (EDS3 System) 5 years (Collection Bags)	**3 years (EDS3 System and Collection Bags)**
Sterilization Method	EtO	Same as predicate
Sterility Assurance Level (SAL)	10^{-6}	Same as predicate
Non-Pyrogenic	Yes	Same as predicate
Packaging	EDS 3 System: product is placed in a blister tray, sealed with a lid, and then placed	Same as predicate

	into a unit box (EDS3 System) Collection Bags: the bags are placed in blister tray sealed with a lid, placed into a unit box. Five (5) blisters per unit box.	

VII. Performance Data

The following performance data has been provided in support of the substantial equivalence determination.

Bench Testing:
Design Verification and Design Validation were performed to verify that the performance of the proposed device is substantially equivalent to that of the predicate device. Please see the Summary of Bench Testing Table below.

Summary of Bench Testing		
Test	**Test Method Summary**	**Result**
IV Pole Clamp Design Verification	Ensure new IV Pole Clamp can hold at least the same amount of weight as the predicate device.	Pass – proposed device design met the acceptance criteria and is therefore substantially equivalent to the predicate device.
Collection Bag Design Verification	Ensure new Collection Bag connects to the EDS 3 system, is leak free, and exhibits at least the same tensile strength as the predicate device.	Pass – proposed device design met the acceptance criteria and is therefore substantially equivalent to the predicate device.
Drainage Time Design Verification	Ensure drainage time for the new system meets design inputs specifications and is at least as fast as the predicate device.	Pass – proposed device design met the acceptance criteria and is therefore substantially equivalent to the predicate device.
Design Validation / Simulated Use of EDS 3 System and Bag	Ensure finished product meets all user inputs and needs and inputs of the predicate device.	Pass – proposed device design met the acceptance criteria and is therefore substantially equivalent to the predicate device.

Sterilization Testing:
The Codman EDS 3 CSF External Drainage System and Collection Bags are sterilized using a validated ethylene oxide sterilization cycles. The sterilization cycle has been validated to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135-1:2014, "*Sterilization of health care products - Ethylene Oxide Sterilization - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.*"

Shelf Life Testing:
The Codman EDS 3 CSF External Drainage System and Collection Bags were subjected to accelerated aging. The aging studies established that the

device and packaging remain functional and maintain sterility for up to 3 years.

Biocompatibility Testing:
Biocompatibility assessments were performed for the material changes (filter, tubing, thumbscrew, and collection bag). All material changes were made to non-patient contacting device components. The proposed materials were determined to be acceptable for their intended use and the final device continues to meet the requirements of ISO 10993-1:2009, *"Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."*

Animal Testing:
No animal studies were performed as appropriate verification and validation of the proposed device was achieved based on the comparison to the predicate device and from the results of the bench testing.

Clinical Testing:
No clinical studies were performed as appropriate verification and validation of the proposed device was achieved based on the comparison to the predicate device and from the results of the bench testing.

Conclusion:
Based on the intended use, fundamental scientific technology, comparison to the predicate device, and testing conducted, it is concluded that the subject device, the Codman EDS 3 CSF External Drainage System and Collection Bags are substantially equivalent to the predicate device and therefore do not raise different questions of safety and effectiveness.