DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 28, 2016

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

Re: K162437
Trade/Device Name: Codman EDS3 CSF External Drainage System
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: September 28, 2016
Received: September 29, 2016

Dear Mr. 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 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 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162437

Device Name
Codman EDS3 CSF External Drainage System

Indications for Use *(Describe)*
Use of the Codman EDS3 CSF External Drainage System 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.

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

I. Submitter

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Raynham, MA 02767

Establishment Registration Number: 1226348

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Secondary Contact: Nancy MacDonald
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Date of Preparation: September 26, 2016

II. Device

Device Proprietary Name	Codman EDS3 CSF External Drainage System
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 the Codman EDS3 CSF External Drainage System (K061568), which was cleared on September 29, 2006.

IV. Device Description

The Codman EDS3 CSF External Drainage System (Codman EDS3 System) is designed to collect cerebral spinal fluid (CSF) from the patient 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 EDS3 device is comprised of four (4) main parts: ventricular catheter, patient drain line, base frame burette tube assembly and a collection bag.

The principle of operation of the proposed Codman EDS3 System is identical to the currently marketed Codman EDS3 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 through the patient line and enters into the 100 mL graduated burette tube assembly, where it is collected over a period of time to calculate a flow rate. The burette tube assembly can then be raised or lowered along the base frame, thereby adjusting the differential pressure to achieve the appropriate flow rate. Once the burette tube height is set, the collected CSF is then drained into the attached 700 ml collection bag.

The EDS3 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 device remains similar to the predicate device. Two changes were made:

1) Anatomical locations of where CSF can be drained was added to the Indications and the statement
2) "fluids of similar characteristics" was removed to enhance clarity since fluid types falling into this category were not specified.

Equivalence Comparison	**Codman EDS3 CSF External Drainage System (Predicate: K061568)**	**Codman EDS3 CSF External Drainage System (Subject of This Submission)**
Indications for Use	Use of the Codman EDS3 CSF External Drainage System is indicated for draining cerebrospinal fluid (CSF) and other fluids of similar physical characteristics as a means of reducing intracranial pressure and CSF volume when the insertion of a permanent, internal shunt is not indicated.	Use of the Codman EDS3 CSF External Drainage System 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.

VI. Comparison to Predicate Device

The proposed Codman EDS3 CSF External Drainage System is identical to the currently marketed Codman EDS3 CSF External Drainage System (K061568) with the exception that this submission proposes use of adhesive Loctite 3924 instead of Loctite 3341 to bond the tubing lines to various components at several joints. The intended use, principle of operation, packaging, shelf life, sterilization method and SAL remain identical to the predicate device.

Substantial Equivalence Comparison		
Characteristic	**Codman EDS3 CSF External Drainage System (Predicate: K061568)**	**Codman EDS3 CSF External Drainage System (Subject of This Submission)**
Manufacturer	Codman & Shurtleff, Inc.	Identical
Classification Panel	Neurology	Identical
Classification Name	Central Nervous System Fluid Shunt and Components (21 CFR 882.5550)	Identical
Indications for Use	Use of the Codman EDS3 CSF External Drainage System is indicated for draining cerebrospinal fluid (CSF) and other fluids of similar physical characteristics as a means of reducing intracranial pressure and CSF volume when the insertion of a permanent, internal shunt is not indicated.	Use of the Codman EDS3 CSF External Drainage System 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.
Operating Principle	Drainage of CSF based on a differential pressure between the patient and the device.	Identical
Implant	No	Identical
Single Use Only	Yes	Identical
Shelf Life	3 years	Identical
Sterilization Method	EtO	Identical
Sterility Assurance Level (SAL)	10^{-6}	Identical
Non-Pyrogenic	Yes	Identical
Packaging	PETG Blister Tray with heat-sealed lid placed into a unit box	Identical

VII. Performance Data

There were no changes made that affect the Codman EDS3 CSF External Drainage System indications for use, principle of operation, manufacturing process, clinical utility, packaging, shelf life, and sterilization. The only difference between the predicate and proposed device is the use of Loctite 3924 instead of Loctite 3341 as the adhesive for bonding the tubing at joints to improve the tensile strength and performance of the tubing line connections.

Bench Testing:
Visual Inspection, Functional Testing (Pressurized Leak and Flow Testing), Mechanical Testing (Tensile Strength and Torque Testing), Shelf Life, and Biocompatibility testing were performed to verify that the performance of the proposed device with adhesive Loctite 3924 is substantially equivalent to that of the current device, which uses adhesive Loctite 3341.

Please see the Summary of Testing Table below for Acceptance Criteria and testing results.

Summary of Testing			
Test	Test Method / Purpose	Acceptance Criteria	Result
Visual Inspection	PIC-CL205063 Ensure finished product meets design specifications.	Pass Visual Standards	Pass
Pressurized Leak and Flow	TM-TM095 Ensure leak free product assembly.	Pass Leak and Flow Test	Pass
Tensile and Torque Testing	TM-TM227 TM-TM100234 Ensure product meets functional specifications.	Pass Tensile and Torque Strength Specification	Pass
Shelf Life	Ensure the product remains functional after sterilization and 3 years of aging.	Meet functional criteria after 2x EtO sterilization and 3 years of aging	Pass
Biocompatibility	ISO 10993 Evaluate the Loctite	Pass Cytotoxicity Testing Pass Irritation and Sensitization	Pass

	3924 material to ensure that it is a safe substitute for Loctite 3341.	Testing No evidence of systemic Toxicity Pass Dermal Irritation Test No evidence of Pyrogenic response No evidence of potential to cause Hemolysis Pass Physiochemical attributes review	

Animal Testing:
No animal studies were required as appropriate verification and validation of the design modifications were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

Clinical Testing:
No clinical studies were required as appropriate verification and validation of the design modifications were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

Conclusion:
Results from performance testing demonstrate that the modified device is suitable for its intended use and did not raise new issues of safety and effectiveness. Based on the indications for use, fundamental scientific technology and a comparison to the predicate device, the subject device Codman EDS3 CSF External Drainage System is substantially equivalent to the predicate device.