DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 3, 2017

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

Re: K172022
Trade/Device Name: Codman HAKIM Precision Valve System, Codman HAKIM Programmable Valve System, Codman HOLTER Lumboperitoneal (LP) Shunt, Codman HOLTER Atrial Catheters, Codman HOLTER Ventricular Catheters, Codman Medos Ventricular Catheter, UNI-SHUNT System, Codman BACTISEAL Catheters
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: June 30, 2017
Received: July 5, 2017

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 (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)*
K172022

Device Name
Codman HAKIM Precision Valve System, Codman HAKIM Programmable Valve System, Codman HOLTER Lumboperitoneal (LP) Shunt, Codman HOLTER Atrial Catheters, Codman HOLTER Ventricular Catheters, Codman Medos Ventricular Catheter, UNI-SHUNT System, Codman BACTISEAL Catheters

Indications for Use *(Describe)*
The Codman HAKIM Precision Valve System is an implantable device that provides constant intraventricular pressure and drainage of cerebral spinal fluid (CSF) for the management of hydrocephalus.

The Codman HAKIM Programmable Valve System is an implantable device that provides constant intraventricular pressure and drainages of cerebral spinal fluid (CSF) for the management of hydrocephalus.

The Codman HOLTER Lumboperitoneal (LP) Shunt is indicated for shunting cerebrospinal fluid when the lumbo-peritoneal route is the procedure of choice in the treatment of communicating hydrocephalus.

The Codman HOLTER Atrial Catheters are indicated for use to shunt cerebrospinal fluid, when shunting of cerebrospinal fluid to the atrium is the procedure of choice in the treatment of hydrocephalus.

The Codman HOLTER Ventricular Catheters are indicated for use to gain access to the ventricles for diagnostic purposes and in the treatment of hydrocephalus.

The Codman Medos Ventricular Catheter is 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 UNI-SHUNT System is indicated for use as a one-piece ventriculo-peritoneal shunt system for the palliative treatment of hydrocephalus. No other use is recommended.

The Codman 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.

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.

510(k) Summary

I. Submitter

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

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

Date of Submission: June 16, 2017

II. Device(s)

Device Proprietary Name(s)	Codman HAKIM Precision Valve System Codman HAKIM Programmable Valve System Codman HOLTER Lumboperitoneal (LP) Shunt Codman HOLTER Atrial Catheters Codman HOLTER Ventricular Catheters Codman Medos Ventricular Catheter UNI- SHUNT System Codman BACTISEAL Catheters
Common Name	Hydrocephalus Shunt System
Classification Name	Central Nervous System Fluid Shunt and Components (21 CFR 882.5550)
Regulatory Classification	II
Product Code	JXG

III. Predicate Device(s)

The predicate devices for this submission have been cleared by the FDA under:

Preamendment – HOLTER Catheters and UNI-SHUNT System
K944222 – Codman HAKIM Shunt System & Ventricular Catheter
K973774 – Codman HAKIM Micro Precision Valve
K974739 – Codman HAKIM Programmable Valve System
K980778 – Codman HAKIM Micro Programmable Valve
K992173 – Codman SiphonGuard CSF Control Device
K020667 – Codman HAKIM Shunt System
K041296 – Modification to HAKIM Precision Valve System
K053350 – Modification to Codman HAKIM Shunt System
K102589 – Codman BACTISEAL Catheters
K122118 – Modification to Codman HAKIM Shunt System

IV. Device Description

Codman HAKIM Precision and Programmable Valves:

The Codman HAKIM Precision and Programmable Valves are implantable devices that provide constant intraventricular pressure and drainage of cerebral spinal fluid (CSF) for the management of hydrocephalus.

Hydrocephalus is a condition caused by the excessive accumulation of CSF in the ventricles of the brain due to a disturbance of CSF secretion, flow, or absorption which causes a rise in intracranial pressure (ICP). To relieve ICP, CSF can be diverted through a shunting device, such as the Codman HAKIM Precision or Programmable Valve, to another body cavity where it is absorbed and subsequently excreted.

Both the Codman HAKIM Precision and Programmable Valves are pressure regulating valves which maintain intraventricular pressure at a constant level. The Codman HAKIM Precision valves are fixed pressure valves and are available in 5 different opening pressure ranges. The Codman HAKIM Programmable Valves, not having fixed pressures, permit non-invasive adjustment of the valve opening pressure. The Codman HAKIM Programmable Valves can be adjusted to 18 different opening pressure settings.

Codman HOLTER Catheters:

The HOLTER Catheter, is a barium-impregnated silicone rubber open-ended catheter. Two stainless steel Type “A” Fixation and Joining Connectors are included with each catheter to use in rejoining the catheter if it has been cut for lengthening or revision.

The HOLTER Catheter, Salmon Design, is a barium-impregnated silicone rubber catheter. Four longitudinal slits (90° apart) near the closed distal tip of the catheter are for drainage of cerebrospinal fluid. Two stainless steel Type “A” Connectors are included with each catheter to use in rejoining the catheter if it has been cut for lengthening or revision.

Codman Medos Ventricular Catheter:

The Medos Ventricular Catheter is made from barium-impregnated silicone tubing. The catheter is 140 mm in length and is supplied with 24 inlet holes, 3 rows of 8 holes, at the proximal end. The catheter, with stainless steel stylet and right angle adapter, is supplied sterile.

UNI-SHUNT® System:

The UNI-SHUNT® system with Reservoir incorporates a double dome access port to facilitate injections and aspirations of CSF samples. It is a continuous length of barium-impregnated silicone tubing with an access reservoir made of self-sealing silicone which can be punctured with a 25 gauge or smaller Huber type needle.

Codman BACTISEAL Catheters:

The BACTISEAL Catheters are made of radiopaque (barium-impregnated) silicone tubing and are supplied sterile. BACTISEAL Catheters are subjected to a treatment process by which the silicone tubing is impregnated with rifampin and clindamycin hydrochloride.

The catheter is 14 cm in length and is supplied with 24 inlet holes (3 rows of 8 holes) at the proximal end. Depth marks have been added to the catheter (one dot at 5 cm and two dots at 10 cm). A stainless-steel stylet and right angle adapter are packaged with the ventricular catheter.

The peritoneal catheter has a beveled tip at one end and the other end of the catheter has a flat tip. The catheter is 120 cm long and may be trimmed to the proper length.

V. Indications for Use

The Codman HAKIM Precision Valve System is an implantable device that provides constant intraventricular pressure and drainage of cerebral spinal fluid (CSF) for the management of hydrocephalus.

The Codman HAKIM Programmable Valve System is an implantable device that provides constant intraventricular pressure and drainages of cerebral spinal fluid (CSF) for the management of hydrocephalus.

The Codman HOLTER Lumboperitoneal (LP) Shunt is indicated for shunting cerebrospinal fluid when the lumbo-peritoneal route is the procedure of choice in the treatment of communicating hydrocephalus.

The Codman HOLTER Atrial Catheters are indicated for use to shunt cerebrospinal fluid, when shunting of cerebrospinal fluid to the atrium is the procedure of choice in the treatment of hydrocephalus.

The Codman HOLTER Ventricular Catheters are indicated for use to gain access to the ventricles for diagnostic purposes and in the treatment of hydrocephalus.

The Codman Medos Ventricular Catheter is 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 UNI-SHUNT System is indicated for use as a one-piece ventriculo-peritoneal shunt system for the palliative treatment of hydrocephalus. No other use is recommended.

The Codman 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.

VI. Comparison to Predicate Device(s)

The HAKIM Precision Valves, HAKIM Programmable Valves, HOLTER Catheters, Medos Ventricular Catheter, UNI-SHUNT System, and BACTISEAL Catheters (hereafter to be referred to as "Codman Hydrocephalus Valves, Catheters & Accessories") are substantially equivalent to their predicate devices. The subject devices have the same indications for use and clinical utility, design principles, materials, sterilization, and packaging as the predicate devices.

The only difference between the predicate and proposed devices is the labeling and IFU. Codman has added the MRI Conditional information to all the impacted products per ASTM F 2503. The HAKIM Precision Valves, HAKIM Programmable Valves, HOLTER Catheters, and UNI-SHUNT System IFU and Labels are also being revised to identify pressure flow or closing pressure characteristics per ISO 7197: 2009. For the slit valves, (HOLTER Catheters and UNI-SHUNT System) closing pressure is identified instead of operating pressure. ISO 7197:2009 section 4.6 describes pressure flow testing, but compliance can also be established by relaying what is most prevalent for product functionality. For the slit valves, the closing pressure values are more prevalent for product functionality.

VII. Performance Data

The following performance data has been provided in support of the substantial equivalence determination. All testing was performed on final sterile devices unless otherwise specified.

Bench Testing

Non-clinical testing was successfully performed to support the proposed MRI labeling information and the ISO 7197 compliance.

Bench Testing Summary		
Standard	Acceptance Criteria	Result
ISO 7197	Characterize the pressure flow characteristics of the device per ISO 7197	Pass – Pressure and Flow characteristic results added to the product IFUs.
ASTM F647	Characterize the long-term stability of the implantable shunt assemblies per ASTM F647. Mean difference of Post stability – pre-stability testing (P-Q post bursting pressure) must not be greater than 10 mmH2O at each pressure setting tested and must comply with PQ characteristic specifications in the IFU.	Pass – average difference less than 10mm H_20 and results comply with characteristics provided in the IFU.
ASTM F2119	Image Artifact information was collected for the devices in both 1.5T and 3.0T MR environments. For each device, scans were made in three planes (sagittal, coronal, and axial) for using both gradient and spin echo sequences. Our labeling lists the worst-case image artifact for gradient echo	Pass – results added to MR Information in the product IFUs.

	sequencing.	
ASTM F2182	The acceptance criterion for this test was to characterize the implanted device increase in temperature after 15 minutes of continuous scanning (in both 1.5 T and 3.0 T MR environments).	Pass – results added to MR Information in the product IFUs.
ASTM F2052	This test assessed if the amount of magnetically induced force on the device is less than or equal to the force on the device due to gravity. The magnetically induced force for the devices was considered to meet the acceptance criteria in both 1.5T and 3.0T MR environment, thus supporting the MR Conditional claim. The maximum acceptable spatial gradient was determined on the basis of the component with the largest deflection, and is listed in our labeling.	Pass – results added to MR Information in the product IFUs.
ASTM F2213	This test assessed if the amount of magnetically induced torque on the device is less than or equal to the gravitational torque. The magnetically induced torque for the	Pass – results added to MR Information in the product IFUs.

	devices was considered to meet the acceptance criteria in both 1.5T and 3.0T MR environments, thus supporting the MR Conditional claim.	

Sterilization
No sterilization studies were performed as there are no changes to the subject devices when compared to the predicates in regards to materials, design, sterilization methods, or SAL. Appropriate sterilization verification was achieved on the predicate devices.

Shelf-Life Testing
No shelf life studies were performed as there are no changes to the subject device when compared to the predicate in regards to materials, design, packaging, or manufacturing processes. Appropriate shelf life verification was achieved based on the predicate devices.

Biocompatibility Testing
No biocompatibility studies were performed as there are no changes to the subject device when compared to the predicate in regards to materials, design, or manufacturing processes. Appropriate biocompatibility verification was achieved on the predicate devices.

Animal Studies
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 Studies
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.

VIII. Conclusion

The proposed Hydrocephalus Valves, Catheters & Accessories, as identified within this submission, are substantially equivalent to the currently marketed

Hydrocephalus Valves, Catheters & Accessories. The MRI testing and ISO 7197 testing did not raise new questions of safety and effectiveness.

The addition of MRI safety and pressure/flow characteristic information to the labeling does not alter the indications for use, intended use, materials of composition, manufacturing and sterilization process, or the fundamental scientific technology of the devices.