K110751

510(k) Summary

MAY - 9 2011

A. Submitter Information

Submitter's name:	Codman & Shurtleff, Inc.
Address:	325 Paramount Drive Raynham, MA 02767
Telephone:	508-880-8349
Fax:	508-977-6428
Contact Person:	Sharon McDermott
Date of Submission:	March 17, 2011

B. Trade/Device Name: CODMAN ® BACTISEAL® Endoscopic Ventricular Catheter
CODMAN ® BACTISEAL® Endoscopic Ventricular Catheter Kit

Common Name: Hydrocephalus catheters

Classification Name: Shunt, Central Nervous System and Components

Regulatory Class: Class II per 21 CFR § 882.5550

Product Code: JXG

C. Predicate Device: Codman® Neuroguide Endoscopic Placement Catheter (K934196)
Codman® Bactiseal ® Catheters (K003322)

D. Device Description: The BACTISEAL Endoscopic Ventricular Catheter is designed to be placed with an endoscope, which functions as the stylet. The endoscope will enable visualization of catheter placement. The tip of the catheter has been slit to allow passage of the endoscope through the catheter tip.

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

The ventricular catheter has an inner diameter of 1.4 mm and an outer diameter of 2.7 mm. 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 right angle adapter is included.

A 120 cm peritoneal catheter is included in the Bactiseal Endoscopic Ventricular Kit along with the ventricular catheter described above. The peritoneal catheter has an inner diameter of 1.0 mm and an outer diameter of 2.2 mm. The catheter can be trimmed to length as needed.

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E. Intended Use: CODMAN® BACTISEAL® Endoscopic Ventricular Catheter is designed for use in the treatment of hydrocephalus when shunting cerebrospinal fluid (CSF) from the ventricles of the brain.

F. Summary of technological characteristics of the proposed to the predicate device.
The technological characteristics of the proposed devices are the exact same as the Codman® Bactiseal® Catheters predicate device. The design modification adds a slit to this device which is the same as the ventricular catheter in the predicate Codman® Neuroguide Endoscopic Placement Catheter. CODMAN® BACTISEAL® Endoscopic Ventricular Catheter is substantially equivalent to the predicate devices based on intended use, performance characteristics, materials, and principles of operation.

G. Performance Data
Bench testingdemonstrated that the slit design allows passage of an endoscope through the slit. The device performs according to its description and intended use and supports the safety and effectiveness of the device. The Bactiseal Endoscopic Ventricualar Catheter conforms to its design specifications and is substantially equivalent to the commercially distributed devices for the same intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Codman & Shurtleff, Inc..
C/O Sharon McDermott
Senior Regulatory Affairs Specialist
325 Paramount Drive
Raynham MA 02767-0350

MAY - 9 2011

Re: K110751
Trade/Device Name: Codman® 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
Dated: March 17, 2011
Received: March 18, 2011

Dear Ms. McDermott:

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.

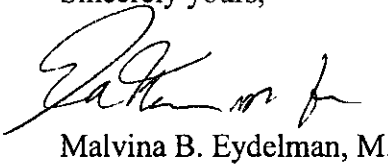
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110751

Device Name: **Codman® BACTISEAL® Endoscopic Ventricular Catheter**

Indications For Use:

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

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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