K090348

510(k) Summary

MAR. - 4 2009

A. Submitter Information

Submitter's name:	Codman & Shurtleff, Inc.
Address:	325 Paramount Drive Raynham, MA 02767
Telephone:	508-880-8349
Fax:	508-828-2777
Contact Person:	Sharon McDermott
Date of Submission:	February 10, 2009

B. Trade/Device Name: CODMAN ® BACTISEAL® EVD Catheter Set
CODMAN ® BACTISEAL® Clear EVD Catheter Set

Common Name: Ventricular catheters

Classification Name: Central Nervous System Fluid Shunt and Components

Regulatory Class: Class II per 21 CFR § 882.5550

Product Code: JXG

C. Predicate Device: CODMAN® BACTISEAL® EVD Catheter Sets (K021653)
CODMAN® BACTISEAL® Barium Striped Catheters (K031123)

D. Device Description: The CODMAN® BACTISEAL® EVD Catheter Set and CODMAN® BACTISEAL® Clear EVD Catheter Set are 1.9 mm inner diameter ventricular catheters packaged with components to facilitate placement and use of the ventricular catheter. Both products are subjected to a treatment process by which the silicone is impregnated with two antimicrobials, rifampicin and clindamycin hydrochloride. Bactiseal silicone catheters have been shown in laboratory studies to reduce the colonization of gram positive bacteria on the tubing surface.

E. Intended Use: The CODMAN® BACTISEAL EVD Catheter Sets and CODMAN® 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

F. Summary of technological characteristics of the proposed to the predicate device.

The technological characteristics of the proposed device are the exact same as the predicate device.

G. Performance Data

Bench testing has been completed and demonstrates that the device performs according to its description and intended use which is the same as the predicate device. All test results demonstrated the substantial equivalence of the product to the commercially distributed devices for the same intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Codman and Shurtleff, Inc.
c/o Ms. Sharon McDermott
Regulatory Affairs Associate II
325 Paramount Drive
Raynham, MA 02767

MAR - 4 2009

Re: K090348
Trade/Device Name: Codman® Bactiseal® EVD Catheter Set and Codman® 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: February 10, 2009
Received: February 11, 2009

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic 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): K090348

Device Name: **Codman® BACTISEAL® EVD Catheter Set and Codman® BACTISEAL® Clear EVD Catheter Set**

Indications For Use:

Codman® BACTISEAL® EVD Catheter Set and Codman® 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.

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

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

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