JUL 2 9 2002

ATTACHMENT A

K 021653

510(k) Summary
Codman BACTISEAL™ EVD Catheter Sets

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767-0350

Contact Person

Kathy Wunder
Regulatory Affairs Specialist
Telephone Number: (508) 880-8351
Fax Number: (508) 828-3212

Name of Device

Proprietary Name: Codman BACTISEAL™ EVD Catheter Sets
Common Name: Ventricular catheters
Classification Name: Catheter, Ventricular

Device Classification

Ventricular Catheters are Class II devices per 21 CFR § 882.4100 (84 JXG).

Statement of Substantial Equivalence

Codman BACTISEAL™ EVD Catheter Sets are substantially equivalent to Codman BACTISEAL™ Catheters, Codman External Drainage Ventricular Catheter Set and Cook Inc. SPECTRUM® Ventricular Catheter, based on the subject device's similarity to the predicate devices in intended use, materials, design, and dimensions.

Indications for Use

The Codman BACTISEAL™ EVD Catheter Set is 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.

Physical Description

Codman BACTISEAL™ EVD Catheter Sets are manufactured from radiopaque silicone rubber which is then impregnated with rifampicin and clindamycin hydrochloride in order to render the device resistant to colonization of most gram positive organisms.

Device Testing

Safety of this device to predicate products relied on extensive performance and *in vitro* testing, biocompatibility studies in accordance with ISO10993-Part 1, and clinical data. All testing results demonstrated the substantial equivalence of the product to 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

JUL 2 9 2002

Ms. Kathy Wunder
Regulatory Affairs Specialist
Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K021653
Trade/Device Name: Codman BACTISEAL™ 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: May 17, 2002
Received: May 20, 2002

Dear Ms. Wunder:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K021653

Device Name **Codman BACTISEAL™ EVD Catheter Set**

Indications For Use:

The Codman BACTISEAL™ EVD Catheter Set is 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.

(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021653

Prescription Use X (Per 21 CFR §801.109) OR Over-the-Counter Use_____

(Optional Format 1-2-96)