K020667

MAR 2 8 2002

510(k) Summary

Submitter:

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

Contact Person:

Elizabeth Dolan
Phone Number: (508) 828-3262
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Date Prepared:

February 28, 2002

Classification Name:

Central Nervous System Fluid Shunt and Components

Proprietary Name:

CODMAN HAKIM™ Shunt Systems

Predicate Devices:

CODMAN HAKIM™ Precision Valve Shunt System (K944222), CODMAN HAKIM™ Micro Precision Valve Shunt System (K973774), CODMAN HAKIM™ Programmable Valve Shunt System (K974739), CODMAN HAKIM™ Micro Programmable Valve Shunt System (K980778), SIPHONGUARD™ CSF Control Device (K992173), and CODMAN BACTISEAL™ catheter (K003322)

Intended Use:

CODMAN HAKIM™ Shunt Systems are implantable devices that provide constant intraventricular pressure and drainage of cerebrospinal fluid for the management of hydrocephalus.

CODMAN HAKIM™ Shunt Systems are available with or without CODMAN BACTISEAL™ catheters, which are intended for use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid is indicated.

CODMAN HAKIM™ Shunt Systems are also available with or without SIPHONGUARD™. The SIPHONGUARD™ device is designed to reduce the potential hazards of excessive lowering of intraventricular pressure (with respect to atmospheric pressure) when a patient is in an upright position.

Materials:

Identical to those of the relevant predicate devices.

Device Description:

The CODMAN HAKIM™ Shunt Systems are variable composite devices, incorporating different configurations of the above-listed predicate devices per the physician's preferences. When placing an order, the physician may choose from the following features: valve type, pressure setting, housing style, reservoir style and base, anti-siphon device, catheter interface, catheter radiolucency, catheter tip style, and catheter anti-microbial treatment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2002

Ms. Elizabeth Dolan
Regulatory Affairs Specialist
Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-00350

Re: K020667
Trade/Device Name: CODMAN HAKIM™Shunt Systems
Regulation Number: 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: II
Product Code: JXG
Dated: February 28, 2002
Received: March 1, 2002

Dear Ms. Dolan:

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 Miriam C. Provost

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

Indications for Use Statement

510(k) Number (if known): K020667

Device Name
CODMAN HAKIM™ Shunt Systems

Indications for Use
CODMAN HAKIM™ Shunt Systems are implantable devices that provide constant intraventricular pressure and drainage of cerebrospinal fluid for the management of hydrocephalus.

CODMAN HAKIM™ Shunt Systems are available with or without CODMAN BACTISEAL™ Catheters, which are intended for use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid is indicated.

CODMAN HAKIM™ Shunt Systems are also available with or without SIPHONGUARD™. The SIPHONGUARD™ device is designed to reduce the potential hazards of excessive lowering of intraventricular pressure (with respect to atmospheric pressure) when a patient is in an upright position.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓
OR
Over-The-Counter Use: _____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020667