510(k) Summary of Safety and Effectiveness

K053107

A. Submitter Information

Submitter's Name: Codman & Shurtleff, Inc.
Address: 325 Paramount Drive
Raynham, MA 02767
Telephone: 508-880-8097
Fax: 508-828-2777
Contact Person: Susan Kagan
Date of Submission: November 2, 2005

B. Trade Name/Device Name: Codman® HAKIM™ Programmable Valve
HAKIM™ Micro Programmable Valve
SIPHONGUARD™ CSF Control Device

Common Name: Hydrocephalus Shunt System

Classification: Central Nervous System Fluid Shunt and Components

Regulation Number: 21 CFR § 882.5550

C. Predicate Device: K041296, HAKIM Precision Valve System, Programmable Valve System, Micro-Programmable Valve System and SIPHONGUARD--Epoxy change
K020667, HAKIM Programmer and Transmitter
K992173, SIPHONGUARD CSF Control Device
K980778, HAKIM Micro Programmable Valve
K974739, HAKIM Programmable Valve

D. Device Description: The Codman HAKIM Programmable Valve (CHPV) is a variable pressure setting hydrocephalus valve, that provides constant intraventricular pressure and drainage of cerebrospinal fluid for the management of hydrocephalus and other conditions in which CSF flow and absorption are impaired. The valve settings can be changed non-invasively by applying an external programming system.

An accessory to the Codman HAKIM Programmable Valve is the SIPHONGUARD CSF Control Device. This flow regulating antisiphon device can be used as an integral component of the Codman HAKIM Programmable Valve shunt system.

E. Intended use: The Codman HAKIM Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CFS for the management of hydrocephalus and other conditions in which CSF flow and absorption are impaired.

The SIPHONGUARD device can be used as a component of hydrocephalus shunt systems to shunt CSF from the ventricles of the brain into the peritoneal cavity or right atrium of the heart. 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.

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

There have been no changes made to the technological characteristics of the device.

G. Performance Data:

Bench testing has been completed and supports the safety and effectiveness of the proposed device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2006

Ms. Susan Kagan
Senior Regulatory Affairs Specialist
Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K053107
Trade/Device Name: HAKIM® Programmable Valve with/without SIPHONGUARD™
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: December 19, 2005
Received: December 21, 2005

Dear Ms. Kagan:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchhop

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 Division
D.O.
f/t:DXY:rrr: 01/13/06

Indications for Use

510(k) Number (if known): K053107

Device Name: Codman® HAKIM® Programmable Valve

Indications For Use:
The Codman HAKIM Programmable Valves (CHPV) are implantable devices that provide constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.

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)

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

510(k) Number K053107

Indications for Use

510(k) Number (if known): K053107

Device Name: SIPHONGUARD CSF Control Device

Indications For Use:

The SIPHONGUARD device can be used as a component of hydrocephalus shunt systems to shunt CSF from the ventricles of the brain into the peritoneal cavity or right atrium of the heart. 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.

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

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