K091346

SECTION 4 510(k) Summary

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: May 6, 2009

JUN - 2 2009

B. Trade/Device Name: Codman Hakim Micro II Valve
Common Name: Shunt
Classification Name: Central Nervous System Fluid Shunt and Components
Regulation Number: 882.550

C. Predicate Device:
Codman Hakim Shunt Systems (K020667)
Hakim Micro Programmable Valve System (K980778)
Codman Hakim Programmable Valve (K974739)
Codman Hakim Micro Precision Valve (K973774)
Codman Hakim Precision Valve (K944222)

D. Device Description:
The Codman Hakim Shunt System incorporates all the possible shunt system features commercially available in the Codman Hakim line of products. The proposed device is adding a dimensional modification to the predicate valves listed above that are part of the Codman Hakim Shunt System.

E. 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.

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

The technological characteristics of the proposed device are substantially equivalent 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Codman & Shurtleff, Inc.
c/o Sharon McDermott
Regulatory Affairs Specialist II
325 Paramount Dr.
Raynham, MA 02767

JUN - 2 2009

Re: K091346
Trade/Device Name: CODMAN® HAKIM® MICRO II Programmable and Precision Valves
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: II
Product Code: JXG
Dated: May 6, 2009
Received: May 7, 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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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.

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

SECTION 3 Indications For Use

510(k) Number (if known): K091346

Device Name: Codman® Hakim® Micro II Progammable Valve
Codman® Hakim® Micro II Precision Valve

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.

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

510(k) Number K091346