K041296

JUN 10 2004

510(k) Summary

Submitter:
Codman and Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02780

Contact Person:
Kathryn Wunder
Phone Number: (508) 880-8351
Fax Number: (508) 828-3212

Date Prepared:
May 13, 2004

Classification Name:
Central Nervous System Fluid Shunt and Components

Proprietary Name:
Item 1: HAKIM™ Precision Valve System
Item 2: HAKIM™ Programmable Valve System
Item 3: HAKIM™ Micro Programmable Valve System
Item 4: SiphonGuard™ CSF Control Device

Predicate Device:
Item 1: HAKIM™ Precision Valve System
Item 2: HAKIM™ Programmable Valve System
Item 3: HAKIM™ Micro Programmable Valve System
Item 4: SiphonGuard™ CSF Control Device

Intended Use:

HAKIM™ Precision Valve System:
The Nonprogrammable Valve System is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.

HAKIM™ (and HAKIM™ Micro) Programmable Valve Shunt System:
The HAKIM™ Programmable Valve Shunt System is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.

SiphonGuard™ CSF Control Device:
The SiphonGuard™ device can be used as a component of hydrocephalus shunt systems designed to shunt CSF from the lateral 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 erect position.

Materials: All materials remain the same for the indicated devices, with the exception of an alternate epoxy. The current epoxy is Stycast 1267. The proposed alternative is Loctite M-31CL.

Device Description: The devices that are the subject of this Special 510(k): Device Modification are identical to their respective predicate predecessors, with the exception of one material component. The proposed alternative epoxy is the single difference in the devices.

Performance Data: This submission relied upon appropriate bench and biocompatibility testing necessary to support the device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2004

Ms. Kathryn Wunder
Regulatory Affairs
Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K041296
Trade/Device Name: HAKIM™ Precision Valve Shunt System
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: May 13, 2004
Received: May 14, 2004

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.

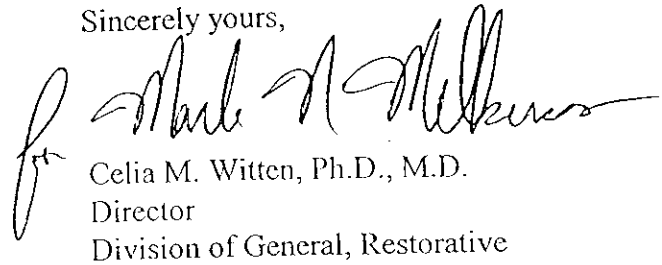
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,



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

510(k) Number (if known): K041296

Device Name: SiphonGuard™ CSF Control Device

Indications For Use:

The SiphonGuard™ device can be used as a component of hydrocephalus shunt systems designed to shunt CSF from the lateral 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)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

510(k) Number K041296

Indications for Use

510(k) Number (if known): K041296

Device Name: HAKIM™ Precision Valve Shunt System

Indications For Use: The HAKIM™ Precision Valve Shunt System is an implantable device that provides 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)

for Mark N Milhous

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

510(k) Number K041296

Indications for Use

510(k) Number (if known): K041296

Device Name: HAKIM™ Micro Programmable Valve Shunt System

Indications For Use: The HAKIM™ Micro Programmable Valve Shunt System is an implantable device that provides 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)

for Mark N Milhous

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

510(k) Number K041296

Indications for Use

510(k) Number (if known): K041296

Device Name: HAKIM™ Programmable Valve Shunt System

Indications For Use: The HAKIM™ Programmable Valve Shunt System is an implantable device that provides 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)

for Mark N Milhauser

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

510(k) Number K041296