

K112156

OCT 17 2011

510(k) Summary

Company Name: Medos International Sarl

Company Address: Chemin-Blanc 38
CH 2400 LeLocle, Switzerland

Contact Person: Jocelyn Raposo
Senior Regulatory Affairs Specialist

Phone: (508) 828-3421

Email: JRaposo@its.jnj.com

Date: July 26, 2011

Name of the Device:

Propriety / Trade Name: Codman Certas Programmable Valve System
Codman Certas Therapy Management System

Common Name: Hydrocephalus Shunt System

Classification: Class II (JXG)
Central Nervous System Fluid Shunt and Components

Legally Marketed Predicate Devices:

K974739 - Codman Hakim Programmable Valve
K091346 - Codman Hakim Shunt System
K992173 - Codman SIPHONGUARD CSF Control Device
K003322 - Codman Bactiseal Catheters
K060681 - Medtronic PS Medical® Strata® Type® Valve
K040943 - Medtronic PS Strata® Valves and Handtools
K090342 - Sophysa Polaris

Device Description: The Certas Programmable Valve System is designed for shunting cerebrospinal fluid (CSF) for the treatment of hydrocephalus. The valve can be set to a choice of eight opening pressure settings for constant intraventricular pressure and drainage of CSF. The Therapy Management System allows the user to non-invasively adjust the opening pressure setting before and after implant.

The Certas Programmable Valve will be available with and without the legally marketed SIPHONGUARD CSF Control Device and the Codman BACTISEAL Catheters.

The Certas Programmable Valve includes the same legally marketed accessories that are available with the Hakim Programmable Valve.

Intended Use:

The Certas Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.

The Certas Therapy Management System allows the noninvasive reading or adjustment of the valve setting.

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.

The BACTISEAL catheters 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.

Technological Comparison:

The Certas Programmable Valve is substantially equivalent to the predicate Hakim Programmable Valve, and the Medtronic Strata and Polaris Sophysa Valves and Adjustment Tool Kits. Substantial equivalence is based on intended use, performance characteristics, materials, and principles of operation.

Performance Data:

Preclinical testing was performed to demonstrate that the Certas Programmable Valve and Therapy Management System performs as intended and is safe and effective. Testing was conducted in accordance with ISO 7197 and included Leak, Pressure-Flow, Overpressure, Bursting Pressure, Dynamic Break Strength, Long-Term Stability and Puncture testing. Magnetic Resonance Imaging (MRI) testing was performed according to ASTM F2052, F2213, F2119, and F2182 for Translational Attraction, Torque, Artifact, and Heating, respectively. The MRI testing demonstrated that the

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Certas valve is MR Conditional in a 3 Tesla MRI system according to ASTM F2503. Biocompatibility was assessed and all of the materials meet the requirements of ISO 10993-1 and FDA Blue Book Memorandum G95-1. Sterilization testing was performed according to ISO 17665 Part 1 and 2 and ISO 11737 demonstrating that a sterility assurance level of 10^{-6} was achieved. The test data establish that the Certas Valve and the Certas Therapy Management System are substantially equivalent to the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT 17 2011

Codman & Shurtleff, Inc.
c/o Jocelyn Raposo
Senior Regulatory Affairs Specialist
325 Paramount Drive
Raynham MA 02767-0350

Re: K112156

Trade/Device Name: Codman Certas Programmable Valve System, Codman Certas Therapy Management System

Regulation Number: 21 CFR 882.5550

Regulation Name: Central nervous system fluid shunt and components

Regulatory Class: Class II

Product Code: JXG

Dated: July 26, 2011

Received: July 27, 2011

Dear Mr. Raposo:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112156

Device Name: CODMAN Certas Programmable Valve
CODMAN Certas Therapy Management System

Indications For Use:

The CODMAN Certas Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.

The CODMAN Certas Therapy Management System allows the noninvasive reading or adjustment of the valve setting.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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