JUL 1 8 2005

510(k) Summary; K050739

CODMAN® VPV™ System

Submitter/Date

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767-0350
Date: July 7, 2005

Contact Person

Karen F. Jurczak
Director, Regulatory Affairs
Telephone Number: (508) 828-3704
Fax Number: (508) 828-2777

Name of Device

Propriety Name:	CODMAN® VPV™ SYSTEM
Common Name:	Hydrocephalus Valve Programmer
Predicate Devices:	HAKIM PROGRAMMER & TRANSMITTER

Device Classification

Class II for Central Nervous System Fluid Shunt and Components devices
21 CFR 882.5550 (84 JXG) – Classification Panel: Neurological

Indications for Use

The Codman VPV System is designed for use only with the Codman HAKIM™ Programmable Valve in the treatment of hydrocephalus when shunting cerebrospinal fluid (CSF) from the ventricles of the brain. It is used to adjust the Codman Programmable Valve to the selected setting ***and provide valve adjustment confirmation. However, radiographic imaging will still be required to confirm the selected setting.***

Device Testing

Substantial equivalence for this device was based upon performance testing (physical and mechanical testing) and *in vitro* testing. All test results demonstrated the substantial equivalence of the product to commercially distributed predicate device for the same intended use.

Statement of Substantial Equivalence

The Codman® VPV™ System is substantially equivalent to the HAKIM PROGRAMMER & TRANSMITTER based on the subject device's similarity to the predicate device including intended use, physical characteristics, and labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 8 2005

Ms. Karen F. Jurczak
Director, Regulatory Affairs
Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K050739
Trade/Device Name: Codman® VPV™ System
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: July 7, 2005
Received: July 8, 2005

Dear Ms. Jurczak:

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,

Miriam C. Provost, Ph.D.
Acting 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): K050739

Device Name: CODMAN® VPV™ System

Indications For Use:

"The system is designed for use only with CODMAN HAKIM Programmable Valves in the treatment of hydrocephalus when shunting cerebrospinal fluid (CSF) from the ventricles of the brain. It is used to adjust the CODMAN HAKIM Programmable Valve to the selected setting ***and provide valve adjustment confirmation. However, radiographic imaging will still be required to confirm the selected setting.***"

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 K050739