MAR 10 1998

K974708

NeuroCare Group™
CAMINO® HEYER-SCHULTE®
NEURO NAVIGATIONAL® REDMOND™

Date: December 16, 1997

Contact: Lori Hays

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: _____

Name: Gemini Standard and Mini Valves

Classification Name: Shunt, Central Nervous System and Components

The Gemini valves are substantially equivalent to other CSF shunting valves currently marketed known as the Heyer-Schulte NeuroCare Low-Profile Valves (LPV, Mini-LPV and ProfileVS), K802586A, and the Heyer-Schulte NeuroCare NOVUS Standard and Mini Valves, K961859, with respect to the functionality, design, placement and use in the neurosurgical arena.

The Gemini Standard and Mini Valves are contoured silicone elastomer valves substantially equivalent to legally marketed predicate devices used for the treatment of hydrocephalic patients when shunting cerebrospinal fluid (CSF) from the ventricles of the brain. The valves incorporate an internal low, medium or high pressure valve assembly which is mounted distal to an integral pumping reservoir for proximal control of CSF flow. The devices also prevent retrograde flow. Integral occluders are incorporated on the proximal and distal ends of the valves. The occluders are designed to manually control the flushing or pumping of CSF proximally or distally. The devices are fitted with a polypropylene needle guard, designed to prevent needle puncture through the valve base during percutaneous injection. The devices contain an integral plastic connector on each end to simplify the attachment of the catheters during the clinical procedure. The devices do not contain any ferrous metal parts which would interfere with magnetic resonance imaging or computerized axial tomography.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 1998

Ms. Lori Hays, MT(ASCP)
Regulatory Submissions Specialist
Heyer-Schulte NeuroCare, L.P.
8401 102nd Street, Suite 200
P.O. Box 390
Pleasant Prairie, Wisconsin 53158-0390

Re: K974708
Trade Name: Gemini Stantard and Mini Valves
Regulatory Class: II
Product Code: JXG
Dated: December 16, 1997
Received: December 17, 1997

Dear Ms. Hays:

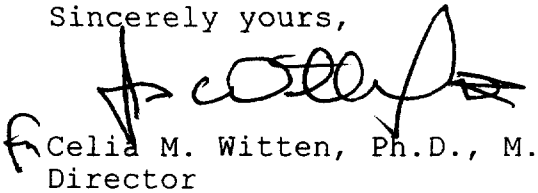
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 8 - DEVICE INDICATIONS FOR USE

510(k) Number (if known): K974708

Device Name: Gemini Standard and Mini Valves

Indications for Use: The Gemini Standard and Mini Valves are utilized in the treatment of hydrocephalic patients. They are components in systems designed to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneal cavity.

This device should only be used by a physician or qualified personnel under the direction of a physician.

Care must be taken to ensure compliance with the manufacturer's instructions for use.

Prescription Use Only
(Per 21 CFR 801.109)

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974708