K972994

NOV - 3 1997

SECTION 2 -510(k) SUMMARY

510(k) Summary:

The determination of safety and efficacy for the Heyer-Schulte NeuroCare External CSF Drainage Management Systems is based on years of clinical history with external drainage systems manufactured from the same materials beginning with the Heyer-Schulte Hermetic External CSF Drainage System (K864676A), which was approved by FDA for market in 1982.

The Heyer-Schulte NeuroCare External CSF Drainage Management Systems are substantially equivalent to other legally marketed products; the P-S Medical Becker External Drainage and Monitoring System, the Codman External Drainage System II, the Heyer-Schulte/Camino Ventricular Drainage System (K932769) and the Heyer-Schulte Hermetic External CSF Drainage System (K864676A) with respect to functionality, design, placement and use.

Hydrocephalic patients with cerebrospinal fluid drainage systems must be kept under close observation for signs and symptoms of changing intracranial pressure due to shunt failure. These signs and symptoms may vary from patient to patient. Increasing intracranial pressure is characterized by headache, vomiting, irritability, listlessness, drowsiness, other signs of deterioration of consciousness and nuchal rigidity. In the infant, increased scalp tension at the anterior fontanelle and congestion of scalp veins will be noted.

Proper placement of the drainage system is critical. Intracranial pressure is controlled only by the height of the system. It is essential that neither the patient nor the drainage system be raised or lowered accidentally. Height changes should only be made by qualified personnel on the orders of the physician.

These products have not been tested for drug compatibility and are not intended for drug administration.

Heyer-Schulte NeuroCare determines substantial equivalence and safety and efficacy of the Heyer-Schulte NeuroCare External CSF Drainage Management Systems based on predicate and currently marketed devices as noted in the summary above.

Lori L. Hays, MT(ASCP)
Regulatory Submissions Specialist

August 11, 1997
Date

* The "K" numbers provided above refer to the 510(k)s previously approved by the FDA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

NOV - 3 1997

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

Re: K972994
Trade Name: External CSF Drainage Management Systems
Regulatory Class: II
Product Code: 84JXG
Dated: August 11, 1997
Received: August 12, 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4648. 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 at (301) 443-6597.

Sincerely yours,

for 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): K972994

Device Name: External CSF Drainage Management Systems

Indications for Use:
The major indication for use of the External CSF Drainage Management Systems is the management of hydrocephalic shunt infections.

If an internal shunt is not indicated, treatment of other cerebral conditions such as pre-operative drainage, intraventricular hemorrhage and post-operative pressure monitoring may also require external drainage to control increased intracranial pressure.

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 X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972994