DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 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: K970983
Trade Name: Peritoneal/Cardiac Hydrocephalic Shunt Catheter
Regulatory Class: II
Product Code: 84JXG
Dated: March 17, 1997
Received: March 18, 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

SECTION 8 - DEVICE INDICATIONS FOR USE

510(k) Number (if known): K970983

Device Name: Peritoneal/Cardiac Catheter

Indications for Use: The Peritoneal/Cardiac Catheter is utilized in the treatment of hydrocephalic patients. It is a component in systems designed to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into either the peritoneal cavity or the right atrium of the heart.

A ventriculoperitoneal shunting system may be indicated to avoid the cardiovascular complications of an atrial shunt or for a hydrocephalic patient in whom an atrial shunt is contraindicated.

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)

Thomas J. Callahan

(Division Sign Off)
...vascular, Respiratory,
...a Devices
...(K) Number K970983