K011812

NOV 0 8 2001

9 510(K) SUMMARY

Merry Lee Bain
Vice President/Director Regulatory Affairs
& Clinical Services
Cook Incorporated
925 South Curry Pike
Bloomington, Indiana, 47402
(812) 339-2235

Trade Name:	SPECTRUM® Ventricular Catheter
Common/Usual Name:	Ventricular Catheter, External Drainage Catheter
Proposed Classification:	Central Nervous System Fluid Shunt and Components 21 CFR Part 882.5550 (84JXG) Class II

The SPECTRUM® Ventricular Catheter is intended for obtaining access to a ventricular cavity of the brain for short-term use to externally drain fluid for the purpose of relieving elevated intracranial pressure or fluid volume. The device will be supplied sterile and is intended for one-time use.
The SPECTRUM® Ventricular Catheter is comparable in terms of intended use and technological characteristics to predicate Ventricular catheters, including Cook Incorporated's Ventricular Catheter. Like the Cook Urological and Cook OB/GYN™ SPECTRUM® Silicone Foley Catheter and the Cook SPECTRUM®/ABRM Catheter for intravascular use, the SPECTRUM® Ventricular Catheter has an antimicrobial component comprised of a combination of minocycline and rifampin.

The SPECTRUM® Ventricular Catheter is a 9 Fr catheter nominally 33 cm in length. The catheter has a closed-end configuration with nominally 16 sideports, and has markings at 1 cm increments to aid in determining depth of placement. The SPECTRUM® Ventricular Catheter is impregnated with an antimicrobial combination of minocycline and rifampin which may reduce the risk of catheter-related infection during use. Based on HPLC analysis, the average amount of minocycline on the catheter is approximately 5 mg (159 Φg/cm), and the average amount of rifampin on the catheter is approximately 4 mg (116 Φg/cm). Components supplied with the SPECTRUM® Ventricular Catheter include a pre-loaded stainless steel stylet, a stainless steel tunneling trocar, and proximal fittings, which are included to facilitate placement and use of the Ventricular Catheter.

The SPECTRUM® Ventricular Catheter is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510(k) substantial equivalency, and has undergone testing to support substantial equivalence. The substantially equivalent determination under the Federal Food, Drug, and Cosmetic Act is not intended to have any bearing whatsoever on the resolution of patent infringement suits or other patent matters.

The device will be manufactured according to specified process controls, undergoing processing, sterilization and packaging procedures similar to predicate devices currently manufactured and marketed by Cook Incorporated.

The SPECTRUM® Ventricular Catheter has undergone biocompatibility testing (Dermal Sensitization, Cytotoxicity, 7 Day Muscle Implantation with Histopathology, Intracutaneous Toxicity, Systemic Toxicity, Hemolysis, Genotoxicity, and a Two Week Brain Implantation Study), physical performance testing, HPLC analysis, zone of inhibition testing, susceptibility testing, and clinical evaluation. Results of this testing provide reasonable assurance of device performance for its intended use.

Clinical Study

To evaluate efficacy of the Cook SPECTRUM® Ventricular Catheter in reducing the incidence of catheter-related infection, a prospective, randomized, multicenter clinical trial was conducted in which patients were enrolled and randomly assigned to receive either a standard non-coated 9 Fr Cook Ventricular Catheter (control arm) or a 9 Fr Cook SPECTRUM® Ventricular Catheter (treatment arm). Of the 288 patients available for follow-up, 149 received the SPECTRUM® Ventricular Catheter and 139 patients received the control catheter. The average duration of catheter placement was 8.5 ± 5.8 days in the treatment group, and 8.2 ± 6.9 days in the control group. Results showed that patients receiving the SPECTRUM® Ventricular Catheter had significantly lower rates of catheter-related infection than those receiving the control catheter (1.3% versus 9.4%, respectively).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 8 2001

Ms. April Lavender, RAC
Vice President, Regulatory Affairs
Cook, Inc.
925 South Curry Pike
P.O. Box 489
Bloomington, Indiana 47402

Re: K011812
Trade/Device Name: SPECTRUM® Vectricular Catheter
Regulation Number: 21 CFR 882.4100
Regulation Name: Ventricular Catheter
Regulatory Class: Class II
Product Code: NHC
Dated: September 5, 2001
Received: September 10, 2001

Dear Ms. Lavender:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

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

Enclosure

NOV 0 8 2001

510(k) Number (if known): K01XXXX K011812

Device Name: **SPECTRUM® Ventricular Catheter**

Indications For Use:

The SPECTRUM® Ventricular Catheter is intended for obtaining access to a ventricular cavity of the brain for short-term use to externally drain fluid for the purpose of relieving elevated intracranial pressure or fluid volume. The device will be supplied sterile and is intended for one-time use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Walker

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011812

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)