AUG 1 2 2004

K033843

COOK®

Cook Incorporated
P.O. Box 489
Bloomington, IN 47402-0489
Phone: 800 468-1379
www.cookgroup.com

510(k) Summary

Submitted by:	Cook Incorporated 750 Daniels Way, P.O. Box 489 Bloomington, IN 47402
Contact Person:	Jennifer J. Bosley, MBA, RAC Ph: (812) 339-2235 Fax: (812) 332-0281
Date Prepared:	August 5, 2004
510(k) #:	**K033843**

Device:

Trade Name:	Spectrum® Central Venous Catheter with or without Hydrophilic Coating
Common/Usual Name:	Central Venous Catheter
Proposed Classification:	Intravascular Catheter, 21 CFR Part 880.5200 (80 FOZ) Class II

Device Description:
The nominal 7-French Triple Lumen Spectrum® Central Venous Catheter with Hydrophilic Coating is a polyurethane catheter with three non-communicating vascular access lumens. The catheter is impregnated with the antimicrobials minocycline and rifampin (avg. concentration 520 µg/cm and 470 µg/cm respectively) and has a hydrophilic coating consisting of polyacrylamide and polyvinylpyrrolidone to enhance insertion.

Intended Use:
The Spectrum® Central Venous Catheter is used for the intravenous administration of nutrient fluids, chemotherapeutic agents and other drugs for therapy, blood sampling, blood delivery, and venous pressure monitoring. The catheter is impregnated with the antimicrobials minocycline and rifampin to help provide protection against catheter-related bloodstream infections (CRBSI). It is not intended to be used as a treatment for existing infections. The device is a short-term use catheter, supplied sterile and intended for one-time use.

Substantial Equivalence:

Manufacturer	Device	510(k) Number
Cook Incorporated	ABRM Central Venous Catheter	K950118

In terms of section 510(k) substantial equivalence, the device is identical in terms of design, intended use and technological characteristics to the predicate Cook ABRM Catheter except for the addition of the hydrophilic coating.

Test Data:
The device has undergone testing that provides reasonable assurance of safety and effectiveness for its intended use. Testing includes: biocompatibility, tensile, vacuum and pressure, flow rate, HPLC and zone of inhibition.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2 2004

Ms. Jennifer Bosley, MBA, RAC
Regulatory Affairs Coordinator
Cook, Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, Indiana 47402-0489

Re: K033843
Trade/Device Name: Spectrum® Central Venous Catheter with or without Hydrophilic Coating
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: June 22, 2004
Received: June 23, 2004

Dear Ms. Bosley:

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 (301) 594-4618. 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/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: **K033843**

Device Name: Spectrum® Central Venous Catheter with or without Hydrophilic Coating

Indications for Use:

The Spectrum® Central Venous Catheter is used for the intravenous administration of nutrient fluids, chemotherapeutic agents and other drugs for therapy, blood sampling, blood delivery, and venous pressure monitoring. The catheter is impregnated with the antimicrobials minocycline and rifampin to help provide protection against catheter-related bloodstream infections (CRBSI). It is not intended to be used as treatment for existing infections. The device is a short-term use catheter, supplied sterile and intended for one-time use.

Prescription Use ___X___ AND/OR Over-The Counter Use ____
(Part 21 CFR 801 Subpart D) (Part 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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K033843