K021557

COOK®

MAY 3 0 2003

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

510(k) Summary

Submitted by:	Cook Incorporated
Contact Person:	Jennifer Bosley, MBA Ph: (812) 339-2235 x2093 Fax: (812) 332-0281
Date Prepared:	March 26, 2003
510(k) #:	K021557
Device:	
Trade Name:	COOK Spectrum® Silicone Catheter
Common/Usual Name:	Intravascular Catheter, Central Venous Catheter
Proposed Classification:	Intravascular Catheter, Therapeutic, Long-term and Short-term 21 CFR Part 880.5970 (80 LJS), Class II 21 CFR Part 880.5200 (80 FOZ), Class II

Device Description:

The COOK Spectrum® Silicone Catheters are single, double or triple lumen central venous catheters; and single and double lumen peripherally inserted central catheters available in sizes ranging from 4Fr single lumen to 12Fr double lumen, including an 8Fr triple lumen device. Catheter lengths range from 8 to 60 cm. The catheter is impregnated with an antimicrobial combination of minocycline and rifampin. The device is supplied sterile and intended for one-time use.

Intended Use:

The COOK Spectrum® Silicone 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. Catheters are available in single and double lumen PICC; and single, double and triple lumen CVC.

Predicate Devices:

The COOK Spectrum® Silicone Catheter is comparable in terms of intended use and technological characteristics to predicate intravascular catheters used to sample blood, administer fluids intravenously, and to monitor venous pressure.

Manufacturer	Device	510(k) Number
COOK Incorporated	Silicone Catheter	A137605
COOK Incorporated	Single Lumen Urethane PICC	K992198
COOK Incorporated	Double Lumen Urethane PICC	K010034
COOK Incorporated	Spectrum® Catheter	K950118
COOK Incorporated	Spectrum® Ventricular Catheter	K011812
COOK Urological/OB/GYN	Spectrum® Silicone Foley Catheter	K000251
Arrow International, Inc.	ARROWgard Blue Plus™ Multi-Lumen CVC	K993691

Substantial Equivalence:

The device will be manufactured according to specified process controls, adhering to Good Manufacturing Practices and Quality System Regulations, undergoing processing, sterilization and packaging procedures similar to devices currently manufactured and marketed by Cook Incorporated. This device is similar with respect to indications for use and design to predicate devices in terms of section 510(k) substantial equivalence.

Test Data:

The COOK Spectrum® Silicone Catheter has undergone biocompatibility, performance, and clinical testing which provide reasonable assurance of safety and effectiveness for its intended use. Testing includes:

- Biocompatibility
- Tensile Testing
- Vacuum and Pressure Testing
- HPLC and Zone of Inhibition Testing
- Flow Testing
- Shelf-Life Testing

Clinical Evaluation:

In this prospective, randomized clinical trial with well matched treatment and control cohorts, results indicate that the COOK Spectrum® Silicone Catheter can significantly reduce the rate of catheter-related bloodstream infection (CRBSI). Clinical safety was evaluated by comparing rates of each complication (other than CRBSI) for the treatment cohort versus the control cohort. To determine effectiveness, the occurrence of definite CRBSI was evaluated as the primary outcome measure. When available, catheters were evaluated after removal from patients by zone of inhibition testing against MRSA (CI4371). Determination of catheter colonization was based on results of any culture from the subcutaneous and tip segment of the catheter using roll plate and sonication culture techniques. Performance was evaluated by comparing the incidence of catheter removal due to catheter leak, bleeding around the catheter, or catheter thrombosis between the two study groups and by comparing the incidence of catheter repositioning.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2003

Ms. Jennifer Bosley, MBA
Regulatory Affairs Coordinator
Cook, Incorporated
925 South Curry Pike
P.O. Box 489
Bloomington, Indiana 47402-0489

Re: K021557
Trade/Device Name: COOK Spectrum® Silicone Catheter
Regulation Number: 880.5200, 880.5970
Regulation Name: Intravascular Catheter, Percutaneous, Implanted, Long-term Intravascular Catheter
Regulatory Class: II
Product Code: FOZ, LJS
Dated: March 26, 2003
Received: March 27, 2003

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,

Susan Runner, DDS, MA
Interim 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 (if known): K021557

Device Name: COOK Spectrum® Silicone Catheter

Indications for Use:

The COOK Spectrum® Silicone 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. Catheters are available in single and double lumen PICC; and single, double and triple lumen CVC. The device is supplied sterile and 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)

Adriana Cavanaugh

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K021557

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)