FEB 2 6 2004

COOK®

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510(k) Summary

Submitted by: Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402

Contact Person: Jennifer Bosley, MBA, RAC
Ph: (812) 339-2235
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Date Prepared: February 13, 2004

510(k) #: **K032274**

Device:
Trade Name: Five Lumen Central Venous Catheter
Common/Usual Name: Central Venous Catheter
Proposed Classification: Intravascular Catheter, Therapeutic, Short-Term, Less than 30 Days
21 CFR Part 880.5200 (80 FOZ) Class II

Device Description:
The Five Lumen Central Venous Catheter is a 10-French radiopaque polyurethane coaxial catheter for short-term use. The catheter is available in lengths of 15 to 30 cm incorporating five round non-communicating vascular access lumens with numbered, colored-coded hubs.

Intended Use:
The Five Lumen 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 intended for short-term vascular access.

Substantial Equivalence:

Manufacturer	Device	510(k) Number
Cook Incorporated	Central Venous Catheter	Pre-Amendment
Maxxim Medical	Argon Multi-Lumen CVC	K984189
Medical Components	Medcomp Quad Lumen CVC	K010021
Arrow International	Multi-Lumen Central Venous Catheter	K904404

In terms of section 510(k) substantial equivalence, the Five Lumen Central Venous Catheter is similar in terms of materials, design, intended use and technological characteristics to predicate multi-lumen intravascular catheters used to sample blood, administer fluids intravenously, and to monitor venous pressure.

Test Data:
The Five Lumen Central Venous Catheter has undergone testing which provide reasonable assurance of safety and effectiveness for its intended use. Testing includes Biocompatibility, Tensile, Vacuum and Pressure, Leakage and Flow Rate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K032274
Trade/Device Name: Cook Five Lumen Central Venous Catheter
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: December 12, 2003
Received: December 15, 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) 594-4646. 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 (if known): K032274

Device Name: Five Lumen Central Venous Catheter

Indications for Use:

The Five Lumen 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 intended for short-term vascular access.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for William Burdick

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

510(k) Number: 032274

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