K060174

510(k) Summary

FEB 17 2006

Submitted By:

Evangeline D. Loh, Ph.D., RAC
Regulatory Affairs Scientist
Cook Incorporated
750 Daniels Way (PO Box 489)
Bloomington, IN 47404 (47402)
812-339-2235
January 23, 2006

Device:

Trade Name:	Cook Incorporated Spectrum® Five Lumen Central Venous Catheter Set
Proposed Classification:	Intravascular Catheter FOZ (21 CFR§880.5200)

Indications for Use

Indicated for use in vascular access to intravenously administer nutrients, fluids, chemotherapeutic agents, and other drugs for therapy, blood sampling, blood delivery, and venous pressure monitoring.

Predicate Devices:

The Spectrum Five Lumen Central Venous Catheter Set is similar in terms of intended use, principles of operation, materials of construction and technological characteristics to predicate devices reviewed as devices for venous access to intravenously administer solutions needed in medical treatment.

Device Description:

The Spectrum Five Lumen Central Venous Catheter Set is a central venous catheter designed to intravenously administer nutrients, fluids, chemotherapeutic agents and other drugs for therapy, blood sampling, blood delivery, and venous pressure monitoring through the vasculature. The Spectrum Five Lumen Central Venous Catheter will be 10 Fr. available in lengths of 15, 20, 25, and 30 cm. The Spectrum Five Lumen Catheter will be impregnated with an average of 683.3 µg/cm minocycline and 564.1 µg/cm rifampin. This device will be supplied sterile and is intended for one-time use.

Substantial Equivalence:

The Spectrum Five Lumen Central Venous Catheter is similar to many devices in commercial distribution for venous access. These devices include the Cook Incorporated Five Lumen Central Venous Catheter Set (D.C. # K032274), Cook Incorporated Spectrum and Spectrum Glide Central Venous Catheter Set (D.C. #K033843), the Arrow International Arrowgard Blue Quad-Lumen Central Venous Catheter (D.C. #K962577), and the Medical Components Medcomp Quad Lumen (D.C.#K010021).

The similar indications for use, principles of operation, technological characteristics, and performance testing results of the Spectrum Five Lumen Central Venous Catheter as compared to the predicate devices support a determination of substantial equivalence.

Test Data:

The Spectrum Five Lumen Central Venous Catheter was subjected to the following tests to assure reliable design and performance under the specified testing parameters.

1. Tensile Testing
2. Shaft Flexibility Testing
3. Shaft Flexural Fatigue Tolerance Testing
4. Gravity Flow Rate Testing
5. Air Leakage Testing
6. Collapsibility under Vacuum Testing
7. Liquid Leakage Testing
8. Burst Pressure Testing
9. Biocompatibility Testing
10. Tensile Testing after Aging
11. Amount of Minocycline and Rifampin Impregnated

The results of these tests provide reasonable assurance that the device conforms to the requirements necessary for its use as a central venous catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2006

Evangeline D. Loh, Ph.D., RAC
Regulatory Affairs Scientist
Cook, Incorporated
750 Daniels Way
Bloomington, Indian 47404

Re: K060174
Trade/Device Name: Cook Incorporated Spectrum® Five Lumen Central Venous Catheter
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: January 23, 2006
Received: January 24, 2006

Dear Dr. Loh:

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.

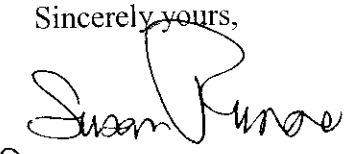
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,



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

Enclosure

510(k) Number (if known): K060174

Device Name: Cook Incorporated Spectrum® Five Lumen Central Venous Catheter Set

Indications for Use: The Spectrum® Five Lumen Central Venous Catheter Set is indicated for the intravenous administration of nutrient fluids, chemotherapeutic agents, and other drugs for therapy, blood sampling, blood delivery, and venous pressure monitoring.

Prescription Use __X___ (Per 21 CFR 801 Subpart D) OR Over–the-Counter Use_____ (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)

[illegible] General Hospital,
[illegible] Devices

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