5. 510(k) Summary

JUL 30 2008

Cook Incorporated Central Venous Catheters
510(k) Summary
21 CFR 807.92

1. Submitter Information:

Applicant:	Cook Incorporated
Address:	750 Daniels Way Bloomington, IN 47404
Phone Number: Fax Number:	(800) 468-1379 (812) 332-0281
Contact: Contact Address:	Susanne Galin, Regulatory Affairs Specialist Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 339-2235 (812) 332-0281

2. Device Information:

Trade Name:	Cook Incorporated Central Venous Catheters and Spectrum/Spectrum Glide Central Venous Catheters
Common Name:	Central Venous Catheters
Classification:	Class II
Product Code:	FOZ (21 CFR Part 880.5200)

3. Predicate Device:

Cook Incorporated's Central Venous Catheters with their expanded indications for use statement are substantially equivalent to the Spectrum Central Venous Catheters with or without Hydrophilic Coating cleared under FDA 510(k) number K033843, the Five Lumen Central Venous Catheter cleared under 510(k) number K032274, and the Spectrum Five Lumen Central Venous Catheter cleared under 510(k) number K060174. They are similar to the Cook Incorporated Central Venous Catheters marketed prior to 1976.

4. Device Description:

Cook Incorporated's Central Venous Catheters incorporate separate, non-communicating vascular access lumens within a single catheter body. These catheters may be impregnated with minocycline and rifampin to help provide protection against catheter-related blood stream infections (CRBSI).

Several sizes are available to allow physicians to choose the catheter that matches anatomical needs of the patient, as well as the number of lumens required for treatment.

Catheter Size (French)	*Number of Lumens*	*Length (cm)*	*Maximum Power Injection Flow Rate (mL/sec)*	*Maximum Safety Cut-off Pressure Limit (psi)*
7	*3*	*15, 20, 25*	*10*	*325*
8	*2*	*15, 20, 25*	*10*	*325*
9	*3*	*15, 20, 25*	*10*	*325*
10	*5*	*15, 20, 25, 30*	*10*	*325*

There have been no changes in the design, dimensions, or materials of the device.

5a. Intended Use for the Cook Central Venous Catheter with or without Heparin:

The Cook Central Venous Catheter with or without Heparin is used for:

- Continuous or intermittent drug infusions
- Central venous blood pressure monitoring (CVP)
- Acute hyperalimentation
- Blood sampling
- Delivery of whole blood or blood products
- Power injection of contrast media*

The device is a short-term use catheter.

* The flow rate of the Cook Central Venous Catheters may not exceed 10 ml/sec.

5b. Intended Use for the Cook Spectrum and Spectrum Glide Central Venous Catheters:

The Cook Spectrum and Spectrum Glide Central Venous Catheter is used for:

- Continuous or intermittent drug infusions
- Central venous blood pressure monitoring (CVP)
- Acute hyperalimentation
- Blood sampling
- Delivery of whole blood or blood products
- Power injection of contrast media*

The activity of the antimicrobial agents, minocycline and rifampin, is localized at the internal and external catheter surface and helps to provide protection against catheter-related bloodstream infections (CRBSI). It is not intended for treatment of existing infection. The device is a short-term use catheter.

* The flow rate of the Cook Spectrum and Spectrum Glide Central Venous Catheters may not exceed 10 ml/sec.

6. Technological Characteristics:

The Cook Central Venous Catheters described in this submission are physically identical to the predicate Central Venous Catheters in terms of technological characteristics (design, dimensions, and materials).

7. Reason for Filing

This submission is for an expansion in the indications for use—a change in labeling only—for Cook Central Venous Catheters. There has been no change to the design, dimensions, or materials of the existing on-market devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2008

Ms. Susanne Galin, RAC
Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way
Bloomington, Indiana 47404

Re: K081113
Trade/Device Name: Cook Spectrum and Spectrum Glide Central Venous Catheters
Cook Central Venous Catheters with or without Heparin
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: July 8, 2008
Received: July 9, 2008

Dear Ms. Galin:

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.

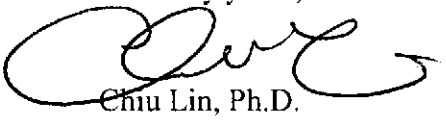
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K081113

Device Name: Cook Central Venous Catheters with or without Heparin

Indications for Use:

The Cook Central Venous Catheter is used for:

- Continuous or intermittent drug infusions
- Central venous blood pressure monitoring (CVP)
- Acute hyperalimentation
- Blood sampling
- Delivery of whole blood or blood products
- Power injection of contrast media*

The device is a short-term use catheter.

* The flow rate of the Cook Central Venous Catheters may not exceed 10 ml/sec.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 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: K081113

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K081113

Device Name: Cook Spectrum and Spectrum Glide Central Venous Catheters

Indications for Use:

The Cook Spectrum and Spectrum Glide Central Venous Catheter is used for:

- Continuous or intermittent drug infusions
- Central venous blood pressure monitoring (CVP)
- Acute hyperalimentation
- Blood sampling
- Delivery of whole blood or blood products
- Power injection of contrast media*

The activity of the antimicrobial agents, minocycline and rifampin, is localized at the internal and external catheter surface and helps to provide protection against catheter-related bloodstream infections (CRBSI). It is not intended for treatment of existing infection. The device is a short-term use catheter.

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Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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