K081690

510(k) Summary

JUL 14 2008

Submitted By:

Nathan Simon, M.S.
Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, PO Box 489
Bloomington, IN 47402
812-339-2235

Device:

Trade Name: Spectrum® Turbo-JeCT™ Peripherally Inserted Central Venous Catheter (PICC)

Proposed Classification: Percutaneous, Implanted, Short- and Long-Term Intravascular Catheter (FOZ and LJS)

Indications for Use:

The Spectrum Turbo-JeCT PICC is indicated for short- or long-term use for venous pressure monitoring, blood sampling, administration of drugs and fluids, and for use with power injectors for delivery of contrast in CT studies. The catheter is impregnated with the antimicrobials minocycline and rifampin to help provide protection against catheter-related bloodstream infections (CRBSIs). The Spectrum Turbo-JeCT PICC is indicated for multiple injections of contrast media through a power injector. The maximum pressure limit setting for power injectors used with the Spectrum Turbo-JeCT PICC may not exceed 325 psi and the flow rate may not exceed the maximum flow rate indicated.

Catheter Size	Maximum Flow Rate*	Injection Pressure Limit Setting
4 Fr Single Lumen	4 ml/sec	325 psi
5 Fr Single Lumen	7 ml/sec	325 psi
5 Fr Double Lumen	5 ml/sec	325 psi

*Flow rates achieved using room temperature Omnipaque 300® contrast and verified using a Medrad Stellant® CT injector system. Omnipaque 300 has a viscosity of 11.8 centipoise at room temperature (20 degrees C). A change in temperature or viscosity of the contrast medium used will result in a change in achievable flow rates.
Omnipaque 300® is a registered trademark of Amersham Health, New Jersey.

Predicate Devices:

The Spectrum Turbo-JeCT PICC Catheter is similar in terms of intended use, materials of construction and technological characteristics to predicate devices Cook Spectrum Silicone Catheter and Cook Turbo-JeCT PICC catheters that were found substantially equivalent under Premarket Notification #K021557, May 30, 2003 and #K072625, December 13, 2007, respectively.

Device Description:
The Spectrum Turbo-JeCT catheter is a radiopaque polyurethane peripherally inserted central venous catheter impregnated with antimicrobials and intended for short- or long-term use. The Spectrum Turbo-JeCT PICCs are 60 cm in length and available in 4 and 5 Fr single lumen and 5 Fr double lumen configurations.

The set components include an introducer needle, wire guide, locking Peel-Away introducer, 12cc syringe, drape, injection cap, catheter fixation device, tape measure, safety scalpel, and a hydrophilic-coated wire guide obturator for non-over-the-wire versions.

Substantial Equivalence:
Cook currently markets the PICC Catheter which is considered substantially equivalent to the Spectrum Turbo-JeCT PICC Catheter. The identical indications for use, principles of operation, similar materials of construction, and technological characteristics of the Spectrum Turbo-JeCT PICC Catheter as compared to the predicate devices support a determination of substantial equivalency.

Test Data:
The Spectrum Turbo-JeCT PICC Catheter was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

1. Flow rate tests
2. Static burst failure pressure tests
3. Cyclic fatigue test
4. Liquid leakage under pressure test
5. Air leakage during aspiration test
6. Tensile strength tests
7. Bond strength tests
8. Stiffness test
9. Shelf life tests
10. Sterility tests
11. Biocompatibility tests

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a PICC catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2008

Mr. Nathan Simon
Regulatory Affairs Specialist
Cook, Incorporated
P.O. Box 489
Bloomington, Indiana 47402

Re: K081690
Trade/Device Name: Spectrum® Turbo-JeCT™ Peripherally Inserted Central Venous Catheter (PICC)
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ, LJS
Dated: June 16, 2008
Received: June 17, 2008

Dear Mr. Simon:

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-***[See Below For Phone Numbers]***. 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

510(k) Number (if known): _____

Device Name: Spectrum® Turbo-JeCT™ Peripherally Inserted Central Venous Catheter (PICC)

Indications for Use:

The Spectrum Turbo-JeCT PICC is indicated for short- or long-term use for venous pressure monitoring, blood sampling, administration of drugs and fluids, and for use with power injectors for delivery of contrast in CT studies. The catheter is impregnated with the antimicrobials minocycline and rifampin to help provide protection against catheter-related bloodstream infections (CRBSIs). The Spectrum Turbo-JeCT PICC is indicated for multiple injections of contrast media through a power injector. The maximum pressure limit setting for power injectors used with the Spectrum Turbo-JeCT PICC may not exceed 325 psi and the flow rate may not exceed the maximum flow rate indicated.

Catheter Size	Maximum Flow Rate*	Injection Pressure Limit Setting
4 Fr Single Lumen	4 ml/sec	325 psi
5 Fr Single Lumen	7 ml/sec	325 psi
5 Fr Double Lumen	5 ml/sec	325 psi

*Flow rates achieved using room temperature Omnipaque 300® contrast and verified using a Medrad Stellant® CT injector system. Omnipaque 300 has a viscosity of 11.8 centipoise at room temperature (20 degrees C). A change in temperature or viscosity of the contrast medium used will result in a change in achievable flow rates.
Omnipaque 300® is a registered trademark of Amersham Health, New Jersey.

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

510(k) Number: K081690

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)