COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

DEC 2 3 2013

510(k) SUMMARY – K133634
Spectrum Turbo-Ject® Peripherally Inserted Central Venous Catheter Set
21 CFR §807.92
Date Prepared: December 09, 2013

Submitted By:

Applicant:	Cook Incorporated
Contact:	Sean Spence, RAC
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x105127
Contact Fax Number:	(812) 332-0281

Device Information:

Trade name:	Spectrum Turbo-Ject® Peripherally Inserted Central Venous Catheter Set
Common name:	PICC Set
Classification Name:	Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulation:	21 CFR §880.5970
Product Code:	LJS

Intended Use:

Spectrum Turbo-Ject® Peripherally Inserted Central Venous Catheter (PICC) Sets and Trays are intended 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 Turbo-Ject PICC may not exceed 325 psi and the flow rate may not exceed the maximum flow rate indicated.

Predicate Devices:

The Spectrum Turbo-Ject® PICC Sets, subject of this submission, are modifications to the following Cook Incorporated PICCs:

- K081690, Spectrum Turbo-Ject® Peripherally Inserted Central Venous Catheter
  - K072625, Turbo-Ject® Peripherally Inserted Central Venous Catheter
    - K132334 & K132885, modifications to add minimal taper design

COOK MEDICAL

COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

Comparison to Predicate Devices:

The scope of this submission is to first add a minimal taper design modification to the 4.0 Fr single and 5.0 Fr single and double lumen antimicrobial (Spectrum) PICCs cleared in the primary predicate, K081690. Second, this submission will add a Spectrum 4.0 Fr double lumen configuration not found in the primary predicate. Complete performance testing, including power injection, was reviewed for a 4.0 Fr double lumen PICC without Spectrum under K072625. Subsequently, the design was modified under K132334 to a minimal taper. Due to market demand, the Spectrum technology from K081690 is being added to the 4.0 Fr double lumen device design cleared under K132334. Lastly, this submission is also meant to standardize the labeling (IFU) format with the non-Spectrum minimally tapered PICCs as amended during K132334 (4.0 Fr) and K132885 (5.0 Fr).

Table 1: Comparison Table

	Cook Spectrum Turbo-Ject PICC K081690[1]	**Cook Spectrum Turbo-Ject PICC Set SUBJECT OF THIS SUBMISSION**
Regulation Number/ Product Code	21 CFR 880.5970, LJS	Identical
Classification Name	Intravascular Catheter	Identical
Class	II	Identical
Intended Use	Intended 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 rated indicated.	Identical
Catheter Shaft Material	Polyurethane	Identical
French Size / Length (cm)	4.0 and 5.0 / 60	Identical
Taper	2 Fr sizes	1 Fr size
Number of Lumens	4.0 Fr – Single lumen 4.0 Fr – Double lumen (K132334) 5.0 Fr – Single lumen 5.0 Fr – Double lumen	4.0 Fr – Single lumen 4.0 Fr – Double lumen 5.0 Fr – Single lumen 5.0 Fr – Double lumen
Flow Rate	4.0 Fr Single lumen – 4 mL/sec 4.0 Fr Double lumen – 3 mL/sec (K132334) 5.0 Fr Single lumen – 7mL/sec 5.0 Fr Double lumen – 5mL/sec	4.0 Fr Single lumen – 5 mL/sec 4.0 Fr Double lumen – 3 mL/sec 5.0 Fr Single lumen – 7mL/sec 5.0 Fr Double lumen – 5mL/sec
Maximum Pressure Rating	325 psi	Identical

COOK MEDICAL

COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

	Cook Spectrum Turbo-Ject PICC K081690[1]	Cook Spectrum Turbo-Ject PICC Set SUBJECT OF THIS SUBMISSION
Antimicrobial Agents	Minocycline • Synonym: Minocin • Chemical family : Tetracycline • Formula : $C_{23}H_{27}N_3O_7 \cdot HCl$ Rifampin • Synonym: Rifampicin • Chemical family : Macrolide antibiotic • Formula : $C_{43}H_{58}N_4O_{12}$	Identical
Antimicrobial Activity Specification	Minimum zone of inhibition of 15 mm	Identical
Method of antimicrobial application	Impregnation	Identical
Inside Diameter (inch)	4.0 Fr Single lumen – 0.030 4.0 Fr Double lumen – 0.022/0.038* (K132334) 5.0 Fr Single lumen – 0.037 5.0 Fr Double lumen – 0.022/0.044*	4.0 Fr Single lumen – 0.037 4.0 Fr Double lumen – 0.022/0.038* 5.0 Fr Single lumen – 0.048 5.0 Fr Double lumen – 0.024/0.048*
Outside Diameter (inch)	4.0 Fr Single lumen – 0.053 4.0 Fr Double lumen – 0.055 (K132334) 5.0 Fr Single lumen – 0.066 5.0 Fr Double lumen – 0.066	4.0 Fr Single lumen – 0.055 4.0 Fr Double lumen – 0.055 5.0 Fr Single lumen – 0.066 5.0 Fr Double lumen – 0.066
Primary set components	Obturator, Peel-Away introducer, entry needles, wire guide, injection caps, syringe, scalpel, and securement device	Identical

[1]K132334 is referenced where appropriate for the 4.0 Fr double lumen device
*height/width

Device Description:

The proposed Spectrum Turbo-Ject® PICCs are radiopaque polyurethane peripherally inserted central venous catheters for short- or long-term use, and can be inserted through a Peel-Away® introducer, or over-the-wire. The proposed devices are minimally tapered 4.0 Fr and 5.0 Fr single and double lumen catheters. The set components may include the PICC, obturator, Peel-Away® introducer, entry needles, wire guide, and other convenience components. The set is supplied sterile and is intended for one-time use.

Test Data:

The following tests were performed to demonstrate that the proposed Spectrum Turbo-Ject® PICC Set met applicable design and performance requirements and support a determination of substantial equivalence.

- Tensile Testing – In conformance with ISO 10555-1:1995, testing demonstrated that the peak load value was greater than 10 N.

COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

- Dynamic Pressure Testing – Testing demonstrated that the catheters did not fail during simulated use.
- Static Failure Pressure – Testing demonstrated that static failure pressure was at or above the acceptance criterion.
- Liquid Leakage Testing – Testing demonstrated that the catheters did not leak liquid.
- Air Leakage Testing – Testing demonstrated that the catheters did not exhibit air leakage.
- Antimicrobial Testing – Testing demonstrated that the catheters met the predetermined acceptance criteria.

Conclusions Drawn from the Tests:

The results of these tests provide reasonable assurance that the Spectrum Turbo-Ject® PICC Set is as safe and effective as the predicate devices and support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 23, 2013

Cook, Incorporated
C/O Mr. Sean Spence, RAC
750 Daniels Way
BLOOMINGTON IN 47404

Re: K133634
Trade/Device Name: Spectrum Turbo-Jet® Peripherally Inserted Central Venous Catheter Set
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: November 25, 2013
Received: November 26, 2013

Dear Mr. Spence:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer
-S FDA for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133634

Device Name
Spectrum (antimicrobial) Turbo-Ject PICCs

Indications for Use *(Describe)*
Spectrum Turbo-Ject Peripherally Inserted Central Venous Catheter (PICC) Sets and Trays are intended 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman
Date: 2013.12.23 14:21:50 -05'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."