COOK MEDICAL

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510(k) SUMMARY – K132334
Turbo-Ject® Peripherally Inserted Central Venous Catheter Set
21 CFR §807.92
Date Prepared: August 01, 2013

Submitted By:

Applicant:	Cook Incorporated
Contact:	Erum B. Nasir or Sean Spence, RAC
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x102607 or x105127
Contact Fax Number:	(812) 332-0281

AUG 16 2013

Device Information:

Trade name:	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:

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 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 Device:

The Turbo-Ject® PICC Sets, subject of this submission, are a modification to the 4.0 Fr devices from the Cook Incorporated Turbo-Ject® PICC (K072625), which was cleared for commercial distribution on December 13, 2007.

Table 1: Comparison to Predicate

	Turbo-Ject PICC: K072625 (Predicate – 4.0 Fr only)	Turbo-Ject PICC Set (Subject Devices)
Classification	21 CFR §880.5970, LJS: Percutaneous, Implanted, Long-Term Intravascular Catheter	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 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 rated indicated.	Identical
Catheter Shaft Material	Polyurethane	Polyurethane
French Size / Length (cm)	4.0 / 60	Identical
Number of Lumens	4.0 Fr – Single lumen 4.0 Fr – Double lumen	Identical
Flow Rate	4.0 Fr Single lumen – 4 mL/sec 4.0 Fr Double lumen – 3 mL/sec	4.0 Fr Single lumen – 5 mL/sec 4.0 Fr Double lumen – 3 mL/sec
Max Pressure Rating	325 psi	Identical
Taper	2 Fr size	1 Fr size
Inside Diameter (inch)	4.0 Fr Single lumen – 0.030 4.0 Fr Double lumen – 0.015/0.035*	4.0 Fr Single lumen – 0.037 4.0 Fr Double lumen –0.022/0.038*
Outside Diameter (inch)	4.0 Fr Single lumen – 0.053 4.0 Fr Double lumen – 0.053	4.0 Fr Single lumen – 0.055 4.0 Fr Double lumen – 0.055
Primary set components	Obturator, Peel-Away® introducer, entry needles, wire guide, injection caps, syringe, scalpel, and securement device	Identical

*height/width

Device Description:

The proposed 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 single and double lumen catheters. A taper is a design element meant to help "wedge" the catheter into the tract by having a transition from a larger Fr size to the labeled Fr size. The proposed minimal taper design provides the same wedge feature only a Δ1 Fr versus Δ2 Fr from the manifold to the labeled Fr size of the catheter. The primary advantage of the 1 Fr size minimal taper is ease of insertion.

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 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.
- Dynamic Pressure Testing – Testing demonstrated that the catheters did not fail during simulated use. Testing revealed the proposed 4.0 Fr single lumen device labeling could be modified to a maximum flow rate of 5 mL/sec from the 4 mL/sec in the predicate labeling.
- Static Failure Pressure - Testing demonstrated that static failure pressure was at or above the acceptance criterion.
- Liquid Leakage Testing – Testing demonstrated that the catheter did not leak liquid.
- Air Leakage Testing – Testing demonstrated that the catheter did not exhibit air leakage.

Conclusions Drawn from the Tests:

The results of these tests provide reasonable assurance that the 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

August 16th 2013

Cook, Incorporated
C/O Mr. Sean Spence
Regulatory Affairs Team Lead
750 Daniels Way
P.O. Box 489
BLOOMINGTON IN 47402-0489

Re: K132334
Trade/Device Name: Turbo-Ject® Peripherally Inserted Central Venous Catheter Set PICC Set
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: July 25, 2013
Received: July 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,

Mary S. Runner -S

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

Enclosure

510(k) Number (if known): K132334

Device Name: Turbo-Ject® PICC Set

Indications for Use:

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 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.

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)

Richard C. Chapman
2013.08.16
13:39:33 -04'00'

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

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