



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

October 7, 2016

Cook Incorporated  
Mr. Steven Lawrie  
Regulatory Affairs Manager  
750 Daniels Way  
Bloomington, Indiana 47404

Re: K161496

Trade/Device Name: Turbo-Flo<sup>®</sup> PICC Sets  
Regulation Number: 21 CFR 880.5970  
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter  
Regulatory Class: II  
Product Code: LJS  
Dated: July 11, 2016  
Received: July 12, 2016

Dear Mr. Lawrie:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

 Tina Kiang  
-S

Tina Kiang, Ph.D.  
Acting Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K161496

Device Name  
Turbo-Flo® PICC Sets

Indications for Use (Describe)

Turbo-Flo Peripherally Inserted Central Venous Catheter (PICC) Sets and Trays are intended for venous pressure monitoring, blood sampling and administration of drugs and fluids.

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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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## 510(k) SUMMARY

**K161496**

**Turbo-Flo® PICC Sets**

**21 CFR § 807.92**

**Date Prepared: October 5, 2016**

### Submitted By:

Submission: Traditional 510(k) Premarket Notification  
Applicant: Cook Incorporated  
Contact: Steven Lawrie  
Applicant Address: Cook Incorporated  
750 Daniels Way  
Bloomington, IN 47404  
Contact Phone Number: (812) 335-3575 x104518  
Contact Fax Number: (812) 332-0281  
Email: RegSubmissions@CookMedical.com

### Device Information:

Trade Name: **Turbo-Flo® PICC Sets**  
Common Name: Catheter, intravascular, therapeutic, long-term greater than 30 days  
Regulation Number: 21 CFR §880.5970  
Regulation Name: Percutaneous, implanted, long-term intravascular catheter  
Regulatory Class: Class II  
Product Code: LJS  
Classification Panel: General Hospital

### Predicate Device:

Trade Name: **Turbo-Flo® PICC**  
510(k) Number: K041848  
Common Name: Catheter, intravascular, therapeutic, long-term greater than 30 days  
Regulation Number: 21 CFR §880.5970  
Regulation Name: Percutaneous, implanted, long-term intravascular catheter  
Regulatory Class: Class II  
Product Code: LJS  
Classification Panel: General Hospital

### Reference Device:

Trade Name: **Turbo-JeCT PICC**  
510(k) Number: K072625  
Common Name: Catheter, intravascular, therapeutic, long-term greater than 30 days  
Regulation Number: 21 CFR §880.5970  
Regulation Name: Percutaneous, implanted, long-term intravascular catheter  
Regulatory Class: Class II

Product Code: LJS  
Classification Panel: General Hospital

**Purpose of the Submission:**

Cook is submitting this premarket notification to obtain FDA's determination that the Turbo-Flo<sup>®</sup> PICC Sets are substantially equivalent to the Turbo-Flo<sup>®</sup> PICC cleared under K041849. The modifications of the subject device as compared to the predicate include changing the depth marking ink printed on the Turbo-Flo<sup>®</sup> PICC catheter shaft and the removal of the power injection indication.

**Device Description:**

The 4 and 5 Fr Turbo-Flo<sup>®</sup> PICC Sets with single or double lumen configurations are radiopaque polyurethane peripherally inserted central venous catheters for short- or long-term use, and can be inserted over-the-wire or through a Peel-Away<sup>®</sup> introducer. The set components may include the PICC, obturator, Peel-Away<sup>®</sup> introducer, entry needles, wire guide, and other convenience components. The set is supplied sterile and is intended for one-time use.

**Intended Use:**

Turbo-Flo<sup>®</sup> Peripherally Inserted Central Venous Catheter (PICC) Sets and Trays are intended for venous pressure monitoring, blood sampling and administration of drugs and fluids.

**Comparison to Predicate Device:**

Turbo-Flo<sup>®</sup> PICC Sets and the predicate device, the Turbo-Flo<sup>®</sup> PICC (K041849), are substantially equivalent in that these devices have the same design, intended use, technological characteristics, method of placement, and included accessories. Both devices are intended for short- or long-term use for venous pressure monitoring, blood sampling, and administration of drugs and fluids.

The modifications of the subject device as compared to the predicate include changing the depth marking ink printed on the Turbo-Flo<sup>®</sup> PICC catheter shaft and the removal of the power injection indication, as shown in the following comparison table.

	<b>Predicate Device</b>	<b>Subject Device</b>	<b>Reference Device</b>
	<b>Turbo-Flo PICC (K041849)</b>	<b>Turbo-Flo PICC</b>	<b>Turbo-JeCT PICC (K072625)</b>
<b>Manufacturer</b>	Cook Incorporated	Cook Incorporated	Cook Incorporated
<b>Regulation</b>	21 CFR §880.5970	Identical	Identical
<b>Class</b>	Class II	Identical	Identical
<b>Product Code</b>	LJS	Identical	Identical
<b>Classification Name</b>	Percutaneous, implanted, long-term intravascular catheter	Identical	Identical
<b>Intended Use/ Indications for Use</b>	<p>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.</p> <p>The maximum pressure setting/limit of power injectors used with the Turbo-Flo PICC may not exceed 300 psi for the 5 Fr single lumen and 200 psi for the 4 Fr single lumen and 5 Fr double lumen. The Turbo-Flo PICC is indicated for a single injection of contrast media through a power injection.</p>	<p>Intended for venous pressure monitoring, blood sampling and administration of drugs and fluids.</p>	<p>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.</p> <p>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.</p>
<b>Duration of Use</b>	Short-term or long-term	Identical	Identical
<b>French Size</b>	4, 5	Identical	Identical
<b>Length (cm)</b>	60	Identical	Identical
<b># of Lumens</b>	Single or Double	Identical	Identical
<b>Shaft Material</b>	Polyurethane	Identical	Identical
<b>Depth Marking</b>	5 cm increments, Imaje #5101 black ink	1 cm increments, Imaje #5135E black ink	1 cm increments, Imaje #5135E black ink
<b>Sterilization</b>	EtO, SAL 10 <sup>-6</sup>	Identical	Identical
<b>Shelf Life</b>	3 years	Identical	Identical
<b>Packaging</b>	Tray with Tyvek lidstock	Identical	Identical

**Performance Data:**

As the ink printed on the subject device is utilized in Cook Turbo-JeCT<sup>®</sup> PICC catheters (K072625) which are also manufactured with polyurethane tubing and undergo the same manufacturing (including ink printing process) and sterilization processes, no testing is warranted for the minor modification on the subject device. In addition, the removal of the power injection, an add-on feature, raises no new questions of safety or effectiveness. Therefore, no performance testing is required for this submission.

**Conclusion:**

The subject device does not raise new questions of safety or effectiveness compared to the predicate device. This supports a determination of substantial equivalence.