DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 9, 2015

Cook, Inc.
David Chadwick, PhD, RAC
Director, Regulatory Affairs/Regulatory Science
750 Daniels Way
Bloomington, Indiana 47404

Re: K133130
Trade/Device Name: Beacon Tip Torcon NB Advantage Catheter, Torcon NB Advantage Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: December 8, 2014
Received: December 9, 2014

Dear David Chadwick, Phd., Rac,

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,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133130

Device Name
Beacon® Tip Torcon NB® Advantage Catheter and Torcon NB® Advantage Catheter

Indications for Use *(Describe)*
The catheters are intended for use in the peripheral and coronary vascular system including the carotid arteries in angiographic procedures by physicians trained and experienced in angiographic techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed.

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

Submitted By:

Applicant:	Cook Incorporated
Address:	750 Daniels Way Bloomington, IN 47404
Contact:	David E. Chadwick, Ph.D., RAC, FRAPS
Email:	david.chadwick@cookmedical.com
Contact Phone Number:	(812) 335-3575 x102330
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	Beacon® Tip Torcon NB® Advantage Catheter and Torcon NB® Advantage Catheter
Common Name:	Diagnostic Intravascular Catheter
Classification Name:	Catheter, Diagnostic Intravascular DQO (21 CFR §870.1200)
Class:	Class II
Device Panel:	Cardiovascular
Date Prepared:	January 5, 2015

Indications for Use:

The catheters are intended for use in the peripheral and coronary vascular system including the carotid arteries in angiographic procedures by physicians trained and experienced in angiographic techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters and wire guides should be employed.

Predicate Devices:

Cook Incorporated's Beacon® Tip Torcon NB® Advantage Catheters and Torcon NB® Advantage Catheters have an identical intended use and are similar in terms of principles of operation, materials of construction, and technological characteristics to the predicate devices. The devices, subject of this submission, are substantially equivalent to the Slip-Cath® Beacon Tip Catheters and the Shuttle® Select Slip-Cath® Catheters, and the Slip-Coat™ Catheters manufactured by Cook Incorporated, which are cleared under 510(k) numbers K122937 and K882796, respectively. They are also substantially equivalent to the Imager II 5F Selective Angiography Catheter manufactured by Boston Scientific Corporation, which is cleared under 510(k) number K121694.

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Comparison to Predicate Devices:

It has been demonstrated that the Beacon® Tip Torcon NB® Advantage Catheters and Torcon NB® Advantage Catheters are comparable to the predicate devices in terms of design, intended use, materials, fundamental technology, and principles of operation.

Device Description:

The Beacon® Tip Torcon NB® Advantage Catheters are visually identified by a distal radiopaque tip bonded onto a nylon catheter shaft with braided stainless steel. Beacon® Tip Torcon NB® Advantage Catheters are available in 4.0, 4.1, 5.0, and 6.0 French with lengths measuring 40 to 170 centimeters. The catheter inner lumen is manufactured to accept a 0.035 or 0.038 inch diameter wire guide. These devices are manufactured without sideports and in a variety of distal tip configurations.

The Torcon NB® Advantage Catheters are selective angiographic catheters manufactured with a thinwall radiopaque nylon material and constructed with stainless steel braiding. The Torcon NB® Advantage Catheters are available in 4.0, 4.1, 5.0, 6.0, 7.0 and 8.0 French with lengths measuring 35 to 150 centimeters. The catheter inner lumen is manufactured to accept a 0.025, 0.035, or 0.038 inch diameter wire guide. These devices are manufactured with zero to twelve sideports, depending on the distal curve radius, and are available in a variety of distal tip configurations. These tips may be tapered at the distal endhole, depending upon device specifications. The catheters are also available in a variety of distal tip configurations.

Beacon® Tip Torcon NB® Advantage Catheters and Torcon NB® Advantage Catheters are for use in angiographic procedures as a conduit for the delivery of contrast media and can help physicians diagnose occlusion or stenosis. The catheters are designed for percutaneous introduction into the vascular system over an appropriately sized wire guide.

Test Data:

The following tests were performed to demonstrate that the Beacon® Tip Torcon NB® Advantage Catheters and Torcon NB® Advantage Catheters met applicable design and performance requirements and support a determination of substantial equivalence.

- Dynamic Flow Rate and Burst Pressure Evaluation – This study is for characterization purposes; therefore no acceptance criteria apply.
- Static Burst Pressure Testing – Testing verified that, in accordance with ISO 10555-2:1996(E), the test articles withstood a minimum of 1200 psig static pressure for at least 2 seconds without failure. The predetermined acceptance criterion was met.
- Evaluation of Dynamic Pressure During Injection after Three Years Accelerated Aging – Testing verified that the test articles achieved a flow rate of at least

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12 mL/sec when pressurized to 1215 psig ± 15 psig without failure. The predetermined acceptance criterion was met.

- Biocompatibility Testing – Per ISO 10993-1:2009, the proposed devices were classified as external communicating devices in contact with circulating blood for a limited (≤ 24 hours) duration. The following tests were completed and the biocompatibility was deemed acceptable: Cytotoxicity, Sensitization, Irritation/Intracutaneous Reactivity, Systemic Toxicity, Hemolysis, Implantation, Partial Thromboplastin Time, C3a Completement Activation, SC5b-9 Complement Activation, Mutagenicity, Pyrogenicity.
- Tensile testing – Testing verified that, under proper clinical use, the peak load values would be greater than 10N, in accordance with ISO 10555-1:2009. The predetermined acceptance criterion was met.
- Liquid Leakage Testing – Testing verified that, in accordance with ISO 10555-1:2013, the catheter maintained a pressure of 300 kPa for 30 seconds without leaking between the catheter shaft and hub. The predetermined acceptance criterion was met.
- Air Leakage Testing – Testing verified that, in accordance with ISO 10555-1:2013, there was no leakage of air between the catheter shaft and hub when subjected to a negative pressure for 15 seconds. The predetermined acceptance criterion was met.
- Particulate Testing - This study is for characterization purposes; therefore no acceptance criteria apply.

In conclusion, the results of these tests support a determination of substantial equivalence to the predicate device.