November 15, 2017

Cook Incorporated
David Chadwick
Director of Regulatory Affairs Science
750 Daniels Way
Bloomington, Indiana 47402

Re: K173289
Trade/Device Name: Beacon Tip Torcon NB Advantage Catheter (HNBR), Slip-Cath Beacon Tip Catheter (SCBR), Shuttle Select Slip-Cath Catheter (SCBR-/-SHTL), Beacon Tip Centimeter Sizing Catheter (CSC), Beacon Tip Cava Vessel Sizing Catheter (CAVA), Beacon Tip White Vessel Sizing Catheter (WSC)
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: October 13, 2017
Received: October 16, 2017

Dear David Chadwick:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kenneth J. Cavanaugh -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)*

K173289

Device Name

Beacon Tip Torcon NB Advantage Catheter (HNBR)
Slip-Cath Beacon Tip Catheter (SCBR)
Shuttle Select Slip-Cath Catheter (SCBR-/-SHTL)
Beacon Tip White Vessel Sizing Catheter (WSC)
Beacon Tip Centimeter Sizing Catheter (CSC)
Beacon Tip Cava Vessel Sizing Catheter (CAVA)

Indications for Use *(Describe)*

The Beacon Tip Catheters (HNBR, SCBR, SCBR-/-SHTL) are intended for use 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.

The Beacon Tip Sizing Catheters (WSC, CSC, CAVA) are intended for use 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. Beacon Tip Sizing Catheters have marker bands that can be used for anatomical measurements.

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)*

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

K173289 – 510(k) SUMMARY

Submitted By: David E. Chadwick, Ph.D., RAC, FRAPS
Cook Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402
Phone: (812) 335-3575 x102330
Fax: (812) 332-0281
Date Prepared: 13 October 2017

Device:

Trade Name:	Beacon® Tip Torcon NB® Advantage Catheter (HNBR) Slip-Cath® Beacon® Tip Catheter (SCBR) Shuttle® Select Slip-Cath® Catheter (SCBR-/-SHTL) Beacon® Tip Centimeter Sizing Catheter (CSC) Beacon® Tip Cava Vessel Sizing Catheter (CAVA) Beacon® Tip White Vessel Sizing Catheter (WSC)
Common Name:	Beacon Tip Catheters and Beacon Tip Sizing Catheters
Classification Name:	Catheter, Intravascular, Diagnostic DQO (21 CFR §870.1200)
Class/Panel:	Class II, Cardiovascular

Indications for Use:

The Beacon Tip Catheters are intended for use 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.

The Beacon Tip Sizing Catheters are intended for use 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. Beacon Tip Sizing Catheters have marker bands that can be used for anatomical measurements.

Predicate Devices:

The subject Beacon Tip Catheter family (Beacon® Tip Torcon NB® Advantage Catheter, Slip-Cath® Beacon® Tip Catheter, and Shuttle® Select Slip-Cath® Catheter) are substantially equivalent to the predicate device, the Slip-Cath® Beacon® Tip Catheter and

the Shuttle® Select Slip-Cath® Catheter cleared on 14 December 2012 under 510(k) Premarket Notification Number K122937.

The subject Beacon Tip Sizing Catheter family (Beacon® Tip Centimeter Sizing Catheter, Beacon® Tip Cava Vessel Sizing Catheter, and Beacon® Tip White Vessel Sizing Catheter) are substantially equivalent to the predicate devices, the White Sizing Catheter, the Aurous Centimeter Sizing Catheter, and the Cava Vessel Sizing Catheter cleared on 26 May 2017 under 510(k) Premarket Notification Number K162448.

Comparison to Predicate Device:

The subject Beacon Tip Catheters and Beacon Tip Sizing Catheters are identical to the predicates (K122937 and K162448, respectively), in that these devices are identical in terms of intended use, principle of operation, basic technological characteristics, and have similar materials of construction. The modifications, which are subject of this submission, include the bonded tip material and packaging.

Device Description:

The Beacon Tip Catheters and Beacon Tip Sizing Catheters subject of this submission are sterile, single use devices designed for use in vascular and non-vascular angiographic procedures. There are three related but unique subfamilies of Beacon Tip Catheters, including: Beacon® Tip Torcon NB® Advantage Catheter, Slip-Cath® Beacon® Tip Catheter, and Shuttle® Select Slip-Cath® Catheter. There are three related but unique subfamilies of Beacon Tip Sizing Catheters, including: Beacon® Tip Centimeter Sizing Catheter, Beacon® Tip Cava Vessel Sizing Catheter, Beacon® Tip White Vessel Sizing Catheter. The subject Beacon Tip Catheters are available in 5.0, 5.5, 6.0 or 6.5 French sizes and are manufactured in lengths of 40 to 125 centimeters. The subject Beacon Tip Sizing Catheters are available in a 5.0 French size and are manufactured in lengths of 70 to 100 centimeters. Each configuration of the subject devices includes a luer lock adapter, connecting cap, and a single lumen shaft. The subject Beacon Tip Sizing Catheters also come with gold marker bands placed at intervals along the distal end of the catheter shaft.

Test Data:

The following tests have been conducted to ensure reliable design and performance under the specified design requirements. These tests include:

- Acute Performance – Testing verified that performance parameters were acceptable for clinical use. The predetermined acceptance criterion was met.
- Biocompatibility testing - cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, pyrogenicity, hemocompatibility, complement activation, and partial thromboplastin time
- Catheter air and liquid leakage – Testing verified that under proper clinical use of the catheter, each test article shall not leak when tested in accordance with BS EN ISO 10555-1, Annex C and D. The predetermined acceptance criteria were met.
- Cyclic bend testing – Testing verified no material degradation after a predetermined set of flex cycles. The predetermined acceptance criteria were met.
- Dimensional verification testing – Testing verified component compatibility and dimensional tolerances.
- Dynamic and static burst testing – Testing verified that under proper clinical use the device can withstand appropriate pressures without signs of failure. The predetermined acceptance criteria were met.
- Packaging performance testing – Testing verified that performance parameters were acceptable for clinical use. The predetermined acceptance criterion was met.
- Radiopacity testing – Testing verified that performance parameters were acceptance for clinical use. The predetermined acceptance criterion was met.
- Tensile testing – Testing verified that under proper clinical use of the catheter, the peak load values shall be in accordance with the applicable values of BS EN ISO 10555-1. The predetermined acceptance criteria were met.

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