March 22, 2019

Cook, Inc.
Reuben Lidster
Regulatory Affairs Specialist
P.O. Box 489, 750 Daniels Way
Bloomington, IN 47402

Re: K181722
Trade/Device Name: Polyethylene Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: February 21, 2019
Received: February 22, 2019

Dear Mr. Lidster:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

For Gregory O'Connell 2019.03.22 11:48:35 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181722

Device Name
Polyethylene Catheter

Indications for Use *(Describe)*
The Polyethylene Catheter is intended for use in angiographic procedures.

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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Polyethylene Catheter
Traditional 510(k) Summary
21 CFR §807.92

Submitter Information

Applicant:	Cook Incorporated
Address:	750 Daniels Way Bloomington, IN 47404
Contact:	Reuben G. Lidster
Email:	RegSubmissions@CookMedical.com
Contact Phone Number:	812-335-3575 ext. 104866
Contact Fax Number:	812-332-0281
Date Prepared:	28 June 2018

Device Information

Trade Name:	Polyethylene Catheter
Common Name:	Diagnostic intravascular catheter
Classification Name:	Catheter, Intravascular, Diagnostic DQO (21 CFR §870.1200)

Predicate Device

The predicate device is the Cook Incorporated Slip-Cath® Beacon® Tip Catheter cleared under 510(k) number K122937 (part number prefix SCBR). The predicate device is manufactured in diameters of 4.0 to 6.5 French and in lengths of 60 to 150 centimeters. The catheter is compatible with a 0.035 or 0.038 inch wire guide. These catheters are manufactured in a variety of distal tip configurations.

Reference Device

Cook has utilized the Angiodynamics AngiOptic® Catheter (K964033) as a reference device, which is available in the 3.0 Fr diameter only, to support the 3.0 Fr diameter size of the subject device, the Polyethylene Catheter.

Cook has utilized the Angiodynamics Soft-Vu® Angiographic Catheter (K161596) as a reference device, which is available in lengths of 25 to 140 centimeters, to support the shorter length (35 centimeters) of the subject device, the Polyethylene Catheter.

Comparison to Predicate Device

The subject device, Polyethylene Catheter has similar indications for use, duration of use, principles of operation, fundamental technological characteristics, and insertion method as the predicate device. Minor differences between the subject device and the predicate device include wording of intended use, material, and dimension. The differences between the subject device and the predicate device do not raise new questions of safety and effectiveness as demonstrated by performance and biocompatibility testing.

Device Description

The Polyethylene Catheter, the subject of this submission, is a sterile, single use device designed for use in angiographic procedures. The Polyethylene Catheter is available in the 3.0 Fr size and is manufactured in lengths of 35, 40, 50, 55 and 65 centimeters. Each configuration includes a Luer lock adapter and a single lumen shaft.

Intended Use

The Polyethylene Catheter is intended for use in angiographic procedures.

Test Data

The Polyethylene Catheter was subjected to the applicable testing listed below to assure reliable design and performance under the testing parameters. Performance and biocompatibility testing were conducted in accordance with applicable FDA guidance documents to confirm the reliable performance of critical device characteristics. Simulated use preconditioning was performed. Packaging integrity and sterility data were leveraged from similar devices manufactured by Cook based on a technical analysis.

- Biocompatibility testing – Testing (i.e., cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, pyrogenicity, hemocompatibility, complement activation, *in vivo* thrombogenicity, and partial thromboplastin time) demonstrated that the device is biocompatible for the intended use. In conformance with the applicable sections of ANSI AAMI ISO 10993-1:2009(R)2013, the predetermined acceptance criteria were met.

- Air Leakage Testing – Testing verified that, under proper clinical use of the catheter, there will be no air leakage when tested in accordance with the methods described in BS EN ISO 10555-1:2013, Annex D. The predetermined acceptance criterion was met.

- Dimensional Verification Testing – Testing verified that the dimensional requirements of the subject device are within a specified tolerance. The predetermined acceptance criteria were met.

- Liquid Leakage Testing – Testing verified that, under proper clinical use of the catheter, there will be no liquid leakage when tested in accordance with the methods described in BS EN ISO 10555-1:2013, Annex C. The predetermined acceptance criterion was met.

- Tensile Testing of the Catheter Shaft – Testing verified that, under proper clinical used of the catheter, the catheter meets the requirements of the methods described in BS EN ISO 10555-1, Annex B. The predetermined acceptance criterion was met.

- Tensile Testing of the Hub-to-Shaft Bond – Testing verified that, under proper clinical use of the catheter, the peak load value of the hub-to-shaft connection is in accordance with the methods of BS EN ISO 10555-1:2013, Annex B. The predetermined acceptance criterion was met.

- Tensile Testing of the Sideported Area – Testing verified that, under proper clinical use of the catheter, the peak load value of the sideported area of the shaft is in accordance with the methods of BS EN ISO 10555-1:2013, Annex B. The predetermined acceptance criterion was met.

- Radiopacity Testing - The results verified, under the proper clinical use of the subject device, the test articles were visible when imaged under fluoroscopy. The predetermined acceptance criterion was met.

Conclusions

The results of testing provide reasonable assurance that the Polyethylene Catheter has been designed so that it conforms to the requirements of its intended use. The evidence demonstrates that the subject device is substantially equivalent to the predicate device, the Cook Incorporated Slip-Cath® Beacon® Tip Catheter (K122937), and does not raise new questions of safety or effectiveness.