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

May 26, 2017

Cook Incorporated
Jessica Swafford
Regulatory Affairs Specialist
750 Daniels Way,
Bloomington, IN 47402 US

Re: K162448
Trade/Device Name: White Sizing Catheter, Aurous Centimeter Sizing Catheter, Cava Vessel Sizing Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: April 14, 2017
Received: April 17, 2017

Dear Jessica Swafford:

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.

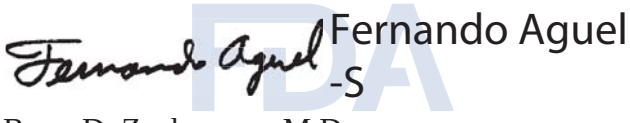
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (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 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,



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)*
K162448

Device Name
White Sizing Catheter, Aurous Centimeter Sizing Catheter, Cava Vessel Sizing Catheter

Indications for Use *(Describe)*
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. 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

5.0 510(k) Summary

Sizing Catheters
Traditional 510(k) Summary
21 CFR §807.92

Submitter Information

Applicant:	Cook Incorporated
Address:	750 Daniels Way Bloomington, IN 47404
Contact:	Jessica Swafford
Email:	RegSubmissions@cookmedical.com
Contact Phone Number:	812-335-3575 ext. 104260
Contact Fax Number:	812-332-0281
Date Prepared:	August 31, 2016

Device Information

Trade Name:	White Sizing Catheter Aurous Centimeter Sizing Catheter Cava Vessel Sizing Catheter
Common Name:	Sizing Catheters
Classification Name:	Catheter, Intravascular, Diagnostic DQO (21 CFR §870.1200)

Predicate Device

The Sizing Catheters are substantially equivalent to the Slip-Cath® Beacon® Tip Catheter cleared under 510(k) number K122937.

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

Comparison to Predicate

It has been demonstrated that the Sizing Catheters and the predicate device are substantially equivalent in terms of intended use, duration of use, principles of operation, fundamental technological characteristics, and insertion method. The design, dimensions, manufacture, and materials of the subject device is either similar to the materials of the predicate device or have been used in other cleared devices. The predicate device is available in 4.0-5.0 French sizes, 40-150 centimeter lengths, and is compatible with a 0.035 or 0.038 inch wire guide; the subject device is available in 4.0 and 5.0 French sizes, 65-100 centimeter lengths, and is compatible with a 0.035 inch wire guide. Therefore, the specifications of the subject device generally fall within the range of specifications of the predicate device in terms of French size, catheter length, and wire guide compatibility. The differences between the subject device and the predicate device, including presence of sideports and addition of a peel-away straightener, do not raise new questions of safety and effectiveness as demonstrated by performance testing.

Device Description

The Sizing Catheters are sterile, single use devices designed for use in angiographic procedures. There are three categories of Sizing Catheters that differ based on the number and spacing of the marker bands, these categories include: White Sizing Catheters, Aurous Centimeter Sizing Catheters, and Cava Vessel Sizing Catheters. All Sizing Catheters are 5.0 French and are manufactured in lengths of 65, 70, 90, and 100 centimeters. Each configuration includes a nylon luer lock adapter and connecting cap, gold marker bands, and a nylon shaft.

Intended Use

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. Sizing catheters have marker bands that can be used for anatomical measurements.

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

Test Data

The Sizing Catheters, subject of this submission, were subjected to applicable testing to assure reliable design and performance under the testing parameters. The following tests were conducted to ensure reliable design and performance:

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

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

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

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

- Static Burst Testing – Testing successfully characterized the catastrophic failure pressure for the catheter is accordance with BS EN ISO 10555-1:2013, Annex F.

- Dimensional Verification Testing – Testing verified that the outer diameter, inner diameter, and marker band spacing of the device is within a specified tolerance. The predetermined acceptance criteria were met.

- Tensile Testing of the Marker Bands – Testing verified that under proper clinical use of the catheter, the peak load value of the marker bands shall be sufficient for clinical use. The predetermined acceptance criterion was met.

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

- Tensile Testing of the Sideports – Testing verified that under proper clinical use of the catheter, the peak load values of the sideported area of the catheter shaft shall be in accordance with the applicable values of BS EN ISO 10555-1:2013, Annex B. The predetermined acceptance criterion was met.

- Flow Rate Testing – Testing successfully characterized the flow rates of the device at designated injection pressures using saline and contrast.

- Acute Performance – Testing verified the performance parameters were acceptable for clinical use. The predetermined acceptance criteria were met.

- Corrosion Testing – Testing verified that the device will not show observable signs of corrosion after being tested in accordance with BS EN ISO 10555-1, Annex A. The predetermined acceptance criterion was met.

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