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

April 28, 2017

Cook Incorporated
Daniel Corbin
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K170616
Trade/Device Name: Van Andel Dilatation Catheter
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator For Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: February 28, 2017
Received: March 1, 2017

Dear Mr. Daniel Corbin:

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,

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)*
K170616

Device Name
van Andel Dilatation Catheter

Indications for Use *(Describe)*
The van Andel Dilatation Catheter is intended to facilitate percutaneous introduction of guide wires, catheters, and other devices into the femoral, popliteal, and infrapopliteal arteries during diagnostic and interventional 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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510(k) SUMMARY

van Andel Dilatation Catheter
Traditional 510(k) Summary
21 CFR §807.92

Submitter Information

Applicant:	Cook Incorporated
Address:	750 Daniels Way Bloomington, IN 47404
Contact:	Daniel J. Corbin
Email:	RegSubmissions@cookmedical.com
Contact Phone Number:	812-335-3575 ext. 104018
Contact Fax Number:	812-332-0281
Date Prepared:	April 12, 2017

Device Information

Trade Name:	van Andel Dilatation Catheter
Common Name:	Dilator, Vessel, For Percutaneous Catheterization
Classification Name:	Vessel dilator for percutaneous catheterization DRE (21 CFR §870.1310)

Predicate Device

The van Andel Dilatation Catheter is substantially equivalent to the Lawmax Dilator, cleared under K123842, and the Fortress Introducer Sheath System, cleared under K153197.

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Comparison to Predicate Device

It has been demonstrated that the van Andel Dilatation Catheter and the predicate devices are substantially equivalent in terms of intended use, duration of use, principles of operation, fundamental technological characteristics, and insertion method. The design, dimensions, indications for use, duration of use, and materials of the subject device is similar to the attributes of the predicate devices. The predicate devices are available in 4.0 - 24.0 French diameters, 26 - 100 centimeter lengths, and are compatible with a 0.035 or 0.038 inch wire guide; the subject device is available in 5.0, 6.3, 7.0, 8.0, and 9.0 French diameters, 60 - 100 centimeter lengths, and is compatible with a 0.035 or 0.038 inch wire guide. Therefore, the specifications of the subject device fall within the range of specifications of the predicate device in terms of French size, catheter length, and wire guide compatibility. This, combined with the provided testing, supports a determination of substantial equivalence between the predicate and subject devices.

Device Description

The van Andel Dilatation Catheter are intravascular dilation catheters comprised of polytetrafluoroethylene, designed for use in diagnostic and interventional procedures. The van Andel Dilatation Catheters are provided sterile and are meant for single use only. The van Andel Dilatation Catheter is available in 5.0, 6.3, 7.0, 8.0, and 9.0 French diameters and is manufactured in lengths of 60, 80, and 100 centimeters.

Intended Use

The van Andel Dilatation Catheter is intended to facilitate percutaneous introduction of guide wires, catheters, and other devices into the femoral, popliteal, and infrapopliteal arteries during diagnostic and interventional procedures.

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Test Data

The van Andel Dilatation Catheter, subject of this submission, was 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 ANSI AAMI ISO 10993-1:2009(R)2013, the predetermined acceptance criteria were met.

- Tensile Testing of the Hub to Shaft Bond – Testing verified that under proper clinical use of the catheter, the hub-to-shaft connection is expected to withstand peak load values specified in BS EN ISO 10555-1:2013 – Section 4.6. The predetermined acceptance criterion was met.

- Liquid Leakage Testing – Testing in accordance with BS EN ISO 10555-1:2013 – Section 4.7.1.verified that under proper clinical use of the catheter, there shall be no liquid leakage. The predetermined acceptance criterion was met.

- Dimensional Verification Testing – Testing verified that the outer diameter, inner diameter, taper length and overall length of the device are within a specified tolerance. The predetermined acceptance criteria were met.

- Exterior Surface Condition Testing and Distal Tip Inspection – Testing verified that exterior surface of the device was smooth and free from any process defects. The predetermined acceptance criteria were met.

- Radiopacity Testing – Testing verified that the device would be visible under fluoroscopic imaging in simulated clinical conditions. The predetermined acceptance criterion was met.

- Kink Radius Testing – Testing verified that the device would not kink under clinical condition in which the test is expected to be used. The predetermined acceptance criteria were met.

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

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