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

February 13, 2017

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

Re: K170193
Trade/Device Name: Advance 14LP Low Profile PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: January 20, 2017
Received: January 23, 2017

Dear Mr. 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,

Fernando Aguel -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)*
K170193

Device Name
Advance 14LP Low Profile PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The Advance® 14LP Low Profile PTA Balloon Dilatation Catheter is intended for percutaneous transluminal angioplasty (PTA) of lesions in peripheral arteries, including iliac, renal, popliteal, infrapopliteal, femoral and iliofemoral, as well as obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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."

510(k) SUMMARY

Submitted By: Daniel J. Corbin
Cook Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402
Phone: (812) 335-3575 x104018
Fax: (812) 332-0281
Date Prepared: January 20, 2017

Device:

Trade Name:	Advance® 14LP Low Profile PTA Balloon Dilatation Catheter
Common Name:	Percutaneous Transluminal Angioplasty Balloon Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal LIT (21 CFR §870.1250)

Indications for Use:

The Advance® 14LP Low Profile PTA Balloon Dilatation Catheter is intended for percutaneous transluminal angioplasty (PTA) of lesions in peripheral arteries, including iliac, renal, popliteal, infrapopliteal, femoral and iliofemoral as well as obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Predicate Device:

The device, subject of this submission, is substantially equivalent to the predicate device, the Advance® 14Rx Rapid Exchange Balloon Catheter, cleared under 510(k) number K090822. The reference device, K130293, the Advance® 18LP Low Profile PTA Balloon Dilatation Catheter has been included in this submission to support the shorter device length.

Comparison to Predicate Device:

It has been demonstrated that the Advance® 14LP Low Profile PTA Balloon Dilatation Catheter is comparable to the predicate device. The Advance® 14LP Low Profile PTA Balloon Dilatation Catheters are identical in terms of intended use, principles of operation, materials of construction, and basic technological characteristics to the predicate device. The predicate device, K090822, was only available with a catheter length of 165 centimeters and the proposed device, the Advance® 14LP Low Profile PTA Balloon Dilatation Catheter, is available with

catheter lengths of 110 and 165 centimeters. The rated burst pressure will increase from 12 atm to 16 atm.

Device Description:

The Advance® 14LP Low Profile PTA Balloon Dilatation Catheters are peripheral (rapid) exchange balloon dilatation catheters that are available with inflated balloon diameters of 2, 2.5, 3, and 4 millimeters and balloon lengths of 20, 40, 60, 80, 120, 160, 200 millimeters. The catheters are supplied sterile and are intended for one-time use.

Test Data:

The following tests were performed to demonstrate that the Advance® 14LP Low Profile PTA Balloon Dilatation Catheters met applicable design and performance requirements and support a determination of substantial equivalence.

- Dimensional Verification – Testing showed that the catheter length was within acceptable tolerance limits. The acceptance criterion was met.
- Balloon Burst Testing – Testing showed that statistically the balloons will burst at or above the minimum rated burst pressure. The acceptance criteria were met.
- Balloon Fatigue Testing – Testing showed that the balloons can withstand ten inflation and deflation cycles to the rated burst pressure of 16 atm. The acceptance criteria were met.

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