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 31, 2016

Cook Incorporated
Mr. Steven Lawrie, MS, MA, RAC
Regulatory Affairs Specialist
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402

Re: K141322
Trade/Device Name: Advance Enforcer 35 Focal Force PTA Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PNO
Dated: February 17, 2015
Received: February 19, 2015

Dear Mr. Lawrie:

This letter corrects our substantially equivalent letter of March 27, 2015.

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 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 yours,

Misti L. Malone -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)*
K141322

Device Name
Advance® Enforcer™ 35 Focal Force PTA Balloon Catheter

Indications for Use *(Describe)*
The Advance® Enforcer™ 35 Focal Force PTA Balloon 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. Not for use in the cerebral or coronary vasculature.

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)*

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

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510(k) SUMMARY

Submitted By:

Steven Lawrie, MS, MA
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Phone: (812) 335-3575 x104518
Fax: (812) 332-0281
Date Prepared: March 24, 2015

Device:

Trade Name:	Advance® Enforcer™ 35 Focal Force PTA Balloon Catheter
Common Name:	PTA Balloon Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal LIT (21 CFR §870.1250)

Indications for Use:

The Advance® Enforcer™ 35 Focal Force PTA Balloon 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. Not for use in the cerebral or coronary vasculature.

Predicate Device:

The device, subject of this submission, is substantially equivalent to the predicate device, the Advance® 35LP Low Profile PTA Balloon Dilatation Catheters cleared under 510(k) numbers K091527 and K132020.

Comparison to Predicate Device:

It has been demonstrated that the Advance® Enforcer™ 35 Focal Force PTA Balloon Catheters are comparable to the predicate device. The Advance® Enforcer™ 35 Focal Force PTA Balloon Catheters are identical in terms of intended use, principles of operation, materials of construction, and basic technological characteristics to the predicate device. An additional catheter length and a modification to the balloon to include four longitudinal ridges have been included. The safety and effectiveness of the modifications are supported by testing.

Device Description:

The Advance® Enforcer™ 35 Focal Force PTA Balloon Catheters are over-the-wire catheters that will be available with inflated balloon diameters of 6, 8, 10, 12 millimeters and a balloon length of 4 centimeters. The balloon includes four polymer elements, which provide focal force upon

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inflation. These elements will aid in opening lesions. The catheters are 5.2 French or 5.7 French, dependent upon device specification, and will be available in lengths of 50, 80, or 135 centimeters. The catheters are compatible with a 0.035 inch (0.89 millimeter) diameter wire guide. The catheters will be supplied sterile and are intended for one-time use.

Test Data:

The following tests were performed to demonstrate that the Advance® Enforcer™ 35 Focal Force PTA Balloon Catheters met applicable design and performance requirements and support a determination of substantial equivalence.

- Compliance Testing – Testing showed that, under simulated body temperature conditions, each balloon met its labeled diameter at the nominal pressure. The acceptance criterion was met.
- Balloon Profile Testing – Testing showed that diameters for each catheter were less than the maximum outside diameter appropriate for the intended sheath size. The acceptance criterion was met.
- Fatigue Testing – Testing showed that the balloons were free from leakage and damage on inflation, withstanding 10 cycles of inflation/deflation. In conformance with the applicable sections of ISO 10555-4, the acceptance criterion was met.
- Balloon Burst Testing – Testing showed that the balloons burst at or above the minimum rated burst pressure, with all failure modes being linear tears. The acceptance criteria were met.
- Balloon Inflation/Deflation Testing – Testing showed that the balloons inflated to rated burst pressure within 60 seconds and fully deflated within 60 seconds. The acceptance criteria were met.
- Sheath Compatibility Testing – Testing showed that the catheters were capable of being inserted and retracted from an appropriately sized sheath without experiencing excessive resistance. The acceptance criterion was met.
- Tensile Strength Testing – Testing showed that under proper clinical use of the device, the peak load values were in accordance with the applicable values of ISO 10555-1. The acceptance criteria were met.
- Soft Tip Integrity Testing – Testing showed that the soft tip did not separate from the catheter, kink, accordion, deform, or show any other anomalies after passage through a clinically relevant model. The acceptance criterion was met.
- Balloon Working Length Testing – Testing showed that the balloon working length for the catheters was matched the labeled length within the expected tolerance. The acceptance criterion was met.
- Simulated Use Testing – The testing showed that the devices were adequate or better in terms of the following performance parameters: preparation, introduction, pushability, trackability, inflatability, deflatability, and interaction with supporting devices.
- Torque Strength – Testing showed that the balloon catheters withstood at least two rotations before failure. The acceptance criterion was met.

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- Dimensional Verification – Testing showed that the catheter inner diameter, catheter length, and catheter profile were all within acceptable tolerances. The acceptance criteria were met.
- Element Effectiveness Testing – Testing showed that the balloons applied at least 20% greater stress in a simulated model than a standard PTA balloon (the predicate PTA5) at a given pressure. The acceptance criterion was met.
- Animal Testing – The testing showed that the devices were adequate or better in terms of the following performance parameters: preparation, introduction, pushability, trackability, flexibility, radiopacity, inflatability, deflatability, interaction with supporting devices, and inspection after use. Testing also showed no significant differences in arterial impact relative to the predicate device.

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