COOK INCORPORATED
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510(k) SUMMARY

Submitted By:

Steven Lawrie, MS, MA
Cook Incorporated
750 Daniels Way
P.O. Box 489
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Phone: (812) 335-3575 x104518
Fax: (812) 332-0281
Date Prepared: October 22, 2013

OCT 25 2013

Device:

Trade Name:	Advance® 35LP Low Profile PTA Balloon Dilatation Catheter
Common Name:	PTA Balloon Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal LIT (21 CFR §870.1250)

Indications for Use:

The Advance® 35LP Low Profile PTA Balloon Dilatation Catheter is indicated 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 Advance® 35LP Low Profile PTA Balloon Dilatation Catheters are identical in terms of intended use, principles of operation, materials of construction, and technological characteristics to the predicate device. Additional combinations of balloon diameter and length have been included. The device, subject of this submission, is substantially equivalent to the Advance® 35LP Low Profile PTA Balloon Dilatation Catheters cleared under 510(k) number K091527.

Comparison to Predicate Device:

It has been demonstrated that the Advance® 35LP Low Profile PTA Balloon Dilatation Catheters are comparable to the predicate device. The predicate device and the device subject of this submission are indicated 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. The predicate device and the proposed device are completely identical in terms of design, intended use, and materials.

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Device Description:

The Advance® 35LP PTA Balloon Dilatation Catheters are over-the-wire catheters that will be available with inflated balloon diameters of 3, 4, 5, 6, 7, 8, 9, 10, and 12 millimeters and balloon lengths of 1.5, 2, 2.5, 3, 4, 6, 8, 10, 12, 14, 17, and 20 centimeters. The catheters are 5.2 French or 5.7 French, dependent upon device specification, and will be available in lengths of 80 and 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® 35LP Low Profile PTA Balloon Dilatation 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 predetermined acceptance criteria were 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 predetermined acceptance criteria were met.
- Balloon 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 predetermined acceptance criteria were met.
- Balloon Burst Testing – Testing showed that the balloons will burst at or above the minimum rated burst pressure, with all failure modes being linear tears. The predetermined 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 predetermined 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 predetermined acceptance criteria were met.
- Tensile Strength Testing – Testing showed that under proper clinical use of the device, the peak load values shall be in accordance with the applicable values of ISO 10555-1. The predetermined acceptance criteria were met.

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

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

October 25, 2013

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

Re: K132020
Trade/Device Name: Advance® 35LP Low Profile PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: LIT
Dated: September 26, 2013
Received: September 27, 2013

Dear Mr. Lawrie:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Special 510(k): Device Modification
PTA Balloon Catheter: Advance® 35LP Low Profile PTA Balloon Dilatation Catheter
Cook Incorporated
June 28 2013

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Indications for Use

510(k) Number (if known): K132020

Device Name: Advance® 35LP Low Profile PTA Balloon Dilatation Catheter

Indications for Use for the Advance® 35LP Low Profile PTA Balloon Dilatation Catheter:

The Advance® 35LP Low Profile PTA Balloon Dilatation Catheter has been designed 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.

Prescription Use __XX__ (Part 21 CFR 801 Subpart D) OR Over-the-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kenneth J. Cavanaugh -S