510(k) Summary

MAY 3 1 2013

Submitted By:

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Cook Incorporated
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812-339-2235
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Device:

Trade Name:	Advance® 18LP Low Profile PTA Balloon Dilatation Catheter
Common Name:	PTA Balloon Catheter
Proposed Classification:	Catheter, Angioplasty, Peripheral, Transluminal (LIT)

Indications for Use:
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 Devices:
Advance® 18LP Low Profile PTA Balloon Dilatation Catheter, K073378, December 28, 2007

Device Description:
The Advance® 18LP Low Profile PTA Balloon Dilatation Catheter is an over-the-wire catheter. The 4 Fr balloon catheter will be compatible with a 0.018 inch wire guide. The balloon catheter will be supplied sterile, intended for one-time use.

Substantial Equivalence:
Cook currently markets the PTA Balloon Catheter which is considered substantially equivalent to the Advance® 18LP Low Profile PTA Balloon Dilatation Catheter. The identical indications for use and technological characteristics of the Advance® 18LP Low Profile PTA Balloon Dilatation Catheter as compared to the predicate device support a determination of substantial equivalence.

Comparison to Predicate Device:
The Advance® 18LP Low Profile PTA Balloon Dilatation Catheter has been modified from the predicate Advance® 18LP Low Profile PTA Balloon Dilatation Catheter to include additional balloon diameters of 2, 9, and 10 mm, additional balloon lengths of 1.5, 2.5, 12, 15, 17, and 20 cm, a catheter length of 150 cm for the over-the-wire type, a peripheral exchange delivery system with single-to-dual lumen configuration and a stainless steel proximal catheter shaft, and usable catheter lengths of 110 and 170 cm for the peripheral exchange type. It has been demonstrated that the Advance® 18LP Low Profile PTA Balloon Dilatation Catheter is comparable to the predicate device in terms of design, intended use, materials, fundamental technology, and principle of operation.

Test Data:
The Advance® 18LP Low Profile PTA Balloon Dilatation Catheter was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

1. Balloon Minimum Burst Strength – Testing shows 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.

2. Balloon Compliance – Testing shows that, under simulated body temperature conditions, each balloon will meet its labeled diameter within tolerance at the nominal pressure. The predetermined acceptance criteria were met.

3. Balloon Profile – Measurement of the diameter of catheter shaft, bonds, and folded balloon shows that the device is compatible with a 4, 5, 6, or 7 Fr sheath (< 0.062, 0.074, 0.087 or 0.100 inch profile). The predetermined acceptance criteria were met.

4. Balloon Fatigue – Testing shows that balloons are free from leakage and damage on inflation, withstanding 10 cycles of inflation/deflation (inflating to rated burst pressure, holding for 30 seconds and deflating). The predetermined acceptance criteria were met.

5. Inflation/Deflation – Testing shows that the balloon will inflate to rated burst pressure within 60 seconds and fully deflate within 60 seconds. The predetermined acceptance criteria were met.

6. Sheath Compatibility – Testing shows that the balloon catheters are compatible with a 4, 5, 6, or 7 Fr sheath. The predetermined acceptance criteria were met.

7. Balloon and Catheter Bond Strength – Testing shows the tensile force during proper clinical use should not fracture or rupture the balloon catheter bond. In conformance with the applicable sections of ISO 10555-1, the predetermined acceptance criteria were met.

8. Shaft Selection Burst Strength – Testing shows the shaft will not burst before the balloon. The predetermined acceptance criteria were met.

9. Kink Radius – Testing shows that the catheters kinked at a radius less than 13 millimeters. The predetermined acceptance criteria were met.

10. Torque Strength – Testing shows that the catheters withstood no less than two rotations before failure. The predetermined acceptance criteria were met.

11. Biocompatibility – Testing (i.e., cytotoxicity, sensitization, irritation, systemic toxicity, hemocompatibility) shows the device is biocompatible. In conformance with the applicable sections of ISO 10993-1, the predetermined acceptance criteria were met.

12. Sterilization – Sterility, bioburden, and residuals testing results met the predetermined acceptance criteria.

In conclusion, the results of these tests support a conclusion that the proposed Advance® 18LP Low Profile PTA Balloon Dilatation Catheter and the predicate device are substantially equivalent.

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, 2013

Cook, Inc.
c/o David E. Chadwick, Ph.D., RAC, FRAPS
Director, Regulatory Affairs/Regulatory Science
750 Daniels Way
Bloomington, IN 47404

Re: K130293
Trade/Device Name: Advance® 18LP Low Profile PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: LIT
Dated: May 2, 2013
Received: May 3, 2013

Dear Dr. Chadwick:

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,

Bram D. Zuckerman -S

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

510(k) Number (if known): _____

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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 __X___ OR Over–the-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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