510(k) Summary

Submitted By:

JUN 12 2009

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750 Daniels Way, PO Box 489
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812-339-2235
April 17, 2009

Device:

Trade Name:	Advance® 35LP Low Profile PTA Balloon Dilatation Catheter
Proposed Classification:	Catheter, Percutaneous (74 DQY)

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:
The Advance® 35LP Low Profile PTA Balloon Dilatation Catheter is similar in terms of intended use, materials of construction, and technological characteristics to predicate devices reviewed as devices for transluminal percutaneous angioplasty of vessel lumens which are narrowed or obstructed.

Device Description:
The Advance® 35LP Low Profile PTA Balloon Dilatation Catheter measures a nominal 5.0 French in outside diameter. Catheter lengths of 80 and 135 cm are available. It is used percutaneously over a pre-positioned wire guide. The proximal end includes a Luer connector which provides access to the end hole lumen and a Luer connector which permits access to the balloon inflation lumen. The catheter incorporates radiopaque markers to assist fluoroscopic visualization of the balloon during use.

Substantial Equivalence:
Cook currently markets the PTA Balloon Catheter which is considered substantially equivalent to the Advance® 35LP Low Profile PTA Balloon Dilatation Catheter. The identical indications for use and similar technological characteristics of the Advance® 35LP Low Profile PTA Balloon Dilatation Catheter as compared to the predicate devices support a determination of substantial equivalency.

Test Data:
The Advance® 35LP 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. Tensile test
2. Balloon inflation/deflation test
3. Balloon burst test
4. Balloon compliance test
5. Balloon fatigue test
6. Bond strength test
7. Animal test
8. Shelf life test
9. Sterility test
10. Biocompatibility test

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a PTA dilatation balloon catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2009

Cook Incorporated
C/O Nathan Simon
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47402

Re: K091527
Trade/Device Name: Advance 35LP Low Profile Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 22, 2009
Received: May 26, 2009

Dear Mr. Simon:

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.

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 go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

510(k) Number (if known): K091527

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

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Prescription Use X (Per 21 CFR 801 Subpart D) OR Over-the-Counter Use ____ (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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091627