APR - 2 2004

K033875

Safety and Effectiveness Information

Submitted By: Karen Bradburn, RAC
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Device: ATB All-Terrain™ Balloon PTA Dilatation Catheter
Percutaneous Catheter (DQY)
21 CFR §870.1250

Predicate Devices:

The ATB All-Terrain™ Balloon PTA Dilatation Catheter is similar in terms of intended use, materials of constructions and technological characteristics to the predicate devices reviewed.

Device Description

The ATB All-Terrain™ Balloon Dilatation Catheter is comprised of a nylon balloon and a nylon shaft. 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 component of this device measures a nominal 5.0 French in outside diameter. The overall catheter lengths of 40, 80 and 120 cm are available. The catheter is offered with inflated balloon diameters of 4, 5, 6, 7, 8, 9 and 10 mm and in lengths of 2, 3, 4, 6 and 8 cm. The catheter incorporates radiopaque markers to assist fluoroscopic visualization of the balloon during use.

Substantial Equivalence

The ATB All-Terrain™ Balloon PTA Dilatation Catheter is similar to many devices in commercial distribution for dilatation and stent deployment. These devices include the ATB All-Terrain PTA Dilatation Catheter, D.C.#K022552, K023504, K031766 and K032931 and the RX Viatrac 14 Peripheral Dilatation Catheter, D.C.#K983055.

The similar indications for use and technological characteristics of the ATB All-Terrain™ Balloon PTA Dilatation Catheter as compared to the predicate devices supports a determination of substantial equivalency.

Performance Data

The following tests have been performed to evaluate the ability of the ATB All-Terrain™ Balloon PTA Dilatation Catheter to perform in accordance with the requirements of the design plan.

- Balloon Minimum Burst Strength Testing
- Balloon Compliance Testing
- Balloon Inflation/Deflation Performance Testing
- Balloon Fatigue Testing
- Bond Strength Testing
- Catheter Hub Tensile Strength Testing
- Diameter and Profile Testing
- Balloon Minimum Burst Strength within a Stent
- Balloon Fatigue within a Stent

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 for peripheral angioplasty and post-dilatation of peripheral vascular stents.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2004

Cook Incorporated
Ms. Karen Bradbum
Regulatory Affairs
P.O. Box 489
Bloomington, IN 47402-0489

Re: K033875
ATB All-Terrain PTA Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Namc: Catheter, Percutaneous
Regulatory Class: Class II (two)
Product Code: DQY
Dated: March 25, 2004
Received: March 26, 2004

Dear Ms. Bradburn:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K033875

Device Name: ATB All-Terrain Balloon PTA Dilatation Catheter

Indications For Use:

For percutaneous transluminal angioplasty of lesions in peripheral arteries including iliac, renal, popliteal, infrapopliteal, femoral and ilio-femoral and are also intended to treat obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The ATB All-Terrain Balloon PTA Dilatation Catheter is also intended for post-dilatation of balloon-expandable peripheral vascular stents.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/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)

Donna R. Vochmel

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033875