OCT 2 2 2003

K032931

510(k) Summary

Submitted By:

Karen Bradburn, RAC
Regulatory Affairs Coordinator
Cook Incorporated
750 Daniels Way, PO Box 489
Bloomington, IN 47402
812-339-2235
September 19, 2003

Device:

Trade Name:	ATB™ All-Terrain Balloon™ PTA Dilatation Catheter
Proposed Classification:	Catheter, Angioplasty, Peripheral, Transluminal (74 DQY)

Predicate Devices:

The ATB™ All-Terrain Balloon™ PTA Dilatation Catheter is similar in terms of intended use, materials of constructions and technological characteristics to predicate devices reviewed as devices for transluminal percutaneous angioplasty of vessel lumens which are narrowed or obstructed.

Device Description:

The ATB™ All-Terrain Balloon™ PTA Dilatation Catheter is an over-the wire balloon catheter indicated 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 device will be made with 5.0 French nylon tubing compatible with an 0.035-inch guidewire. It will be supplied sterile, intended for one-time use.

Substantial Equivalence:

This device will be manufactured according to specified process controls and a Quality Assurance Program. This device will undergo packaging similar to the devices currently marketed and distributed by Cook Incorporated. This device will undergo sterilization similar to the devices currently marketed and distributed. Being similar with respect to indications for use, materials and physical construction to predicate devices, this device meets the requirements for section 510(k) substantial equivalence.

Test Data:

The ATB™ All-Terrain Balloon™ PTA 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 tests
2. Balloon deflation tests
3. Balloon burst tests
4. Balloon compliance
5. Balloon fatigue tests
6. Balloon profile

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

OCT 2 2 2003

Cook, Incorporated
c/o Ms. Karen Bradburn, RAC
Regulatory Affairs Coordinator
750 Daniels Way
P.O. Box 489
Bloomington, Indiana 47402

Re: K032931
Trade Name: ATB™ All-Terrain Balloon™ PTA Dilatation Catheter
Regulation Number: 21 CFR §870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: September 19, 2003
Received: September 22, 2003

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) 594-4646. 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,

for 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): K032931

Device Name: PTA Balloon 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over–the-Counter Use _____
(Per 21 CFR 801.109)

Elizabeth Mahler
(Division Sign-Off)
Division of Cardiovascular Devices

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K032931