K082933

NOV - 3 2008

Passeo-35 PTA Catheter
Special 510(k) Premarket Notification

1. 510(K) SUMMARY

Name and Address of Sponsor:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Establishment Registration Number: 1028232

Applicant Name and Address:

BIOTRONIK AG
Ackerstraße 6
8180 Bülach
Switzerland

Device Name:

Proprietary Name:	Passeo-35
Common Name:	Percutaneous Transluminal Angioplasty (PTA) Catheter
Classification:	Class II (21 CFR 870.1250)
Classification Name:	Catheter, angioplasty, peripheral, transluminal
Product Code:	DQY

Date Prepared: November 3, 2008

General Description:

The Passeo-35 peripheral transluminal angioplasty (PTA) balloon catheter is indicated for dilatation of stenotic segments in peripheral vessels. One radiopaque marker is located at either end of the balloon to facilitate fluoroscopic visualization and positioning of the balloon catheter towards and across the lesion. The dilatation balloon is designed to inflate to a known diameter at a specific inflation pressure consistent with the compliance chart on the label. The balloon catheter includes a tapered soft tip to facilitate advancement of the catheter.

The balloon catheter shaft has two Luer ports at the proximal end. One port (inflation port) serves for connecting an inflation device to inflate/deflate the balloon. The other port (guidewire port) enables insertion of the guide wire. The balloon catheter is a dual lumen design with both lumens contained within one tube. The smaller lumen is the balloon inflation/deflation lumen. The larger lumen permits the use of guide wires with a maximum diameter of 0.035" to facilitate advancement of the Passeo-35 catheter towards and through the lesion(s) to be dilated. The balloon catheter is compatible with introducer sheath (introducer) sizes according to the recommendations on the label. The balloon catheter has a silicone coating to improve the trackability and pushability characteristics.

Predicate Devices:

BIOTRONIK proposes the following PTA catheters cleared through 510(k) notifications as the predicate devices for the Passeo-35 PTA Catheter:

- BIOTRONIK's Pheron PTA Catheter (K033217, cleared October 31, 2003 and K052757, cleared October 28, 2005)
- BIOTRONIK's Passeo-18 PTA Catheter (K072765, cleared December 12, 2007)

Indication for Use:

The Passeo-35 peripheral dilatation catheter is indicated to dilate stenosis in the renal, iliac, femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Name and Address of Manufacturer:
BIOTRONIK AG (reg. no. 8043892)
Ackerstrasse 6
8180 Bülach, Switzerland

Manufacturer's Registration Number: 8043892

Manufacturing Site Contact Person and Phone Number:
Marcel Schaefer
BIOTRONIK AG
Ackerstraße 6
8180 Bülach, Switzerland
011-41-44-864-51-78
marcel.schaefer@biotronik.com

510(k) Contact Person and Phone Number:
Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035
Phone: (888) 345-0374
Fax: (503) 635-9936
jon.brumbaugh@biotronik.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2008

Biotronik, Inc.
c/o Mr. Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
6024 Jean Road
Lake Oswego, OR 97035

Re: K082933
Trade/Device Name: Passeo-35 PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (Two)
Product Code: DQY
Dated: September 30, 2008
Received: October 1, 2008

Dear Mr. Brumbaugh:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Donna R. Vachuska

Bram D. 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): K082933

Device Name: Passeo-35 PTA Catheter

Indications For Use:

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

Donna R. Vochman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082933

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