Passeo-18 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

DEC 1 2 2007

Applicant Name and Address:

Biotronik AG.
Ackerstraße 6
8180 Bülach
Switzerland

Establishment Registration Number: 8043892

Device Name:

Proprietary Name:	Passeo-18
Common Name:	Percutaneous Transluminal Angioplasty (PTA) Catheter
Classification:	Class II (21 CFR 870.1250)
Classification Name:	Percutaneous Catheter
Product Code:	LIT
510(k) Number:	

Date Prepared: September 27, 2007

General Description:

The Passeo-18 peripheral transluminal angioplasty (PTA) balloon catheter is indicated for dilatation of stenotic segments in peripheral vessels. Two radiopaque markers are 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 enables insertion of the guide wire. The balloon catheter has a two lumen co-axial design. The outer lumen is the balloon inflation/deflation lumen. The inner lumen permits the use of guide wires with diameters up to a maximum of 0.018" to facilitate advancement of the balloon 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 its Pheron peripheral PTA catheter cleared through the following 510(k) notifications as the predicate device for the Passeo-18 PTA Catheter:

- K033217, cleared October 31, 2003
- K052757, cleared October 28, 2005

Indication for Use:

The Passeo-18 peripheral dilatation catheter is indicated to dilate stenosis in the femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Name and Address of Manufacturing Site:

BIOTRONIK AG (reg. no. 8043892)
Ackerstrasse 6
8180 Bülach, Switzerland

Manufacturing Site Contact Person and Phone Number:

Marcel Schaefer
BIOTRONIK AG
Ackerstraße 6
8180 Bülach, Switzerland
011-41-44-864-51-78

510(k) Contact Person and Phone Number:

Jon Brumbaugh
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035
(888) 345-0374

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2 2007

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

Re: K072765
Trade/Device Name: Passeo-18
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: LIT
Dated: November 13, 2007
Received: November 14, 2007

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,

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): K072765

Device Name: Passeo-18 PTA catheter

Indications For Use: Passeo-18 is indicated to dilate stenosis in the femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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. Vichinsky

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072765