MAR 2 - 2005

Galeo Focus Coronary Guide Wire
Additional Information for 510(k) #K042373

1. 510(k) Summary

Name and Address of Sponsor:

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

Establishment Registration Number: 1028232

Device Name:

Proprietary Name Galeo Focus Guide Wire
Classification Class II (21 CFR 870.1330)
Classification Name Catheter Guide Wire
Product Code DQX

General Description and Predicate Devices:

BIOTRONIK's Galeo Focus family of guide wires includes steerable coronary guide wires with various tip flexibilities and configurations that are intended to guide the placement of intravascular catheters with compatible guide wire lumens during PTCA or other therapeutic or diagnostic procedures. The Galeo Focus guide wires are substantially equivalent to BIOTRONIK's GALEO Guide Wires (#K982272, cleared 01-08-99) and Galeo Hydro Guide Wires (#K001736, cleared 08-02-00).

The Galeo Focus Guide Wires are identical in design and materials and functionally equivalent to the Galeo and Galeo Hydro Guide Wires already cleared for distribution, with the exception that the guide wire consists of 3 radiopaque marker bands on the distal tip for lesion length assessment starting at 37 mm proximal to the guide wire tip. Additionally, the distal 27 mm of the guide wire are covered with a highly radiopaque platinum coil. The number, dimensions and spacing of the markers on the distal tip of the Galeo Focus are the same as the legally marketed ATW Marker Wire from Cordis Corporation (#K994358, cleared 01-13-00) with the exception that the first distal marker is located 37 mm proximally from the tip versus 45 mm for Cordis' ATW.

Indications for Use:

Galeo coronary guide wires are indicated to facilitate the placement of balloon dilation catheters or other interventional devices with compatible guide wire lumen during an interventional procedure.

Name and Address of Manufacturing Site:

BIOTRONIK GmbH & Co. KG (reg. no. 9610139)
Woermannkehre 1, 12359 Berlin, Germany
011-49-30-689-05-304

Contact Person and Phone Number:

Jon Brumbaugh
Director, Regulatory Affairs and Compliance
Phone (888) 345-0374 Fax (503) 635-9936
jon.brumbaugh@biotronikusa.com

Name and Address of Contract Manufacturing Site:

BIOTRONIK AG (reg. no. 8043892)
Ackerstrasse 6
8180 Bülach, Switzerland
011-41-1-864-5247

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 - 2005

Mr. Jon Brumbaugh
Director, Regulatory Affairs and Compliance
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Re: K042373
Trade/Device Name: Galeo Focus Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: II
Product Code: DQX
Dated: February 22, 2005
Received: February 23, 2005

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 Office of Compliance at (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

Diana R. Vochmer

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): K042373

Device Name: Galeo Focus Guide Wire

Indications For Use:

Galeo coronary guide wires are indicated to facilitate the placement of balloon dilation catheters or other interventional devices with compatible guide wire lumen during an interventional procedure.

Prescription Use ___✓___ (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. Vachney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042373