K110163

FEB 25 2011

510(k) Summary

Submitted By:

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Device:

Trade Name:	Approach Pro ST Wire Guide
Proposed Classification:	Wire, Guide, Catheter 21 CFR §870.1330

Indications for Use:

The Approach Pro ST Wire Guide is indicated for use in facilitating delivery of percutaneous catheters into the peripheral vasculature.

Predicate Devices:

The Approach Pro ST Wire Guide is a modification of the Approach Pro LT Wire Guide, D.C. #K070410, which was cleared for commercial distribution on April 27, 2007.

Device Description:

The Approach Pro ST Wire Guide consists of a stainless steel core wire coated with polytetrafluoroethylene (PTFE). The outside diameter of the Approach Pro ST Wire Guide is 0.014 inches and the device will be available in 135 cm, 190 cm, and 300 cm lengths. It will be supplied sterile and intended for one-time use.

Substantial Equivalence:

The Approach Pro ST Wire Guide is similar to many devices in commercial distribution for facilitating delivery of percutaneous catheters into the peripheral vascular system. The Approach Pro ST Wire Guide is a modification of the Approach Pro LT Wire Guide, D.C. #K070410, which was cleared for commercial distribution on April 27, 2007. The Approach Pro LT and Approach Pro ST Wire guides share identical indications for use, principles of operation, technological characteristics, and similar materials of construction, supporting a determination of substantial equivalence.

Test Data:

The Approach Pro ST Wire Guide was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests included:

1. Three Point Bend Test
2. Corrosion Resistance Test
3. Radiopacity Evaluation
4. Evaluation of Torque Response and Torque Strength
5. Tensile Evaluation of the Distal Tip
6. Characterization of Loads Required to Deflect the Distal Tip
7. Evaluation of Resistance to Fracture
8. Evaluation of Resistance to Fracture after 3-Year Accelerated Aging
9. Evaluation of Resistance to Damage by Flexing
10. Evaluation of Resistance to Damage by Flexing after 3-Year Accelerated Aging
11. Biocompatibility Testing
12. Pyrogen Testing
13. Bioburden Testing
14. Endotoxin Testing
15. EtO Residual Testing

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 wire guide.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Re: K110163
Trade/Device Name: Approach Pro ST Wire Guide
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: January 18, 2011
Received: January 27, 2011

Dear Dr. Santner:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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): D.C. #K110163

Device Name: Approach Pro ST Wire Guide

Indications for Use: For use in facilitating delivery of percutaneous catheters into the peripheral vasculature.

Prescription Use X OR Over-the-Counter Use
(Per 21 CFR 801 Subpart D) (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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110163