510(k) Summary

FEB 25 2011

General Company Information

Name TechDevice Corporation

Address 650 Pleasant Street
Watertown, MA 02472

Contact: Gary Bunnewith

Telephone: 617-972-5810

General Device Information

Product Name: Endologix Guidewire

Common Name: Guidewire

Classification:
DQX, Catheter guide wire 21 CFR 870. 1330

Predicate Devices
Guidewire K053251
TechDevice Corporation
Watertown, MA 02472

Guidewire K053028
TechDevice Corporation
Watertown, MA 02472

Product Description:
The Guidewire is constructed of a stainless steel core wire and a platinum coil welded/brazed in place over the core wire. The coil may cover the entire core wire or just the floppy distal portion. The exposed core wire and or the coil may be uncoated stainless steel or coated with a PTFE spray or a PTFE jacket. Platinum Tungsten marker bands may be placed under the coil to aid in visualization.

Indications for Use:
The Guidewire facilitates placement and exchange of catheters and other instruments in the peripheral vasculature. This guidewire is not intended for use in the coronary arteries or neurovasculature.

Safety and Performance:
Substantial equivalence for this device was based on a comparison of labeling, physical and performance design characteristics as compared to the predicate device, as well as on the results of comparative bench testing. Comparative performance testing included:

A. Tensile Strength
B. Torque Strength
C. Torqueability
D. Tip Flexibility
E. Coating Integrity
F. Corrosion Testing

Substantial Equivalence

The proposed guidewires are substantially equivalent to the currently marketed guidewires which were cleared for marketing by FDA under K053251 and K053258. Substantial equivalence for the proposed devices is based on a comparison of materials, dimensional specifications, design characteristics, labeling and indications for use. The two guidewires are of the exact same design and the only changes are the heat annealing process going from ambient air to vacuum and alternative labeling (i.e. naming) requested for the two wires. Physical testing has been conducted to confirm the proposed products performance characteristics.

Conclusion:

Based on the indications for use, technological characteristics, and comparison to predicate devices, the Guidewires have been shown to be safe and effective for its intended use.

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

TechDevice Corporation
C/O Gary Bunnewith
Director of Quality
650 Pleasant Street
Watertown, MA 02472

FEB 25 2011

Re: K110241
Trade/Device Name: Endologix Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: January 19, 2011
Received: January 27, 2011

Dear Mr. Gary Bunnewith:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 (301) 796-7100 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): K110241

Device Name: Endologix Guidewire

Indications for Use:

The Guidewire facilitates placement and exchange of catheters and other instruments in the peripheral vasculature. This guidewire is not intended for use in the coronary arteries or neurovasculature.

Prescription Use X AND/OR Over-the -Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart D)

(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 K110241