510(k) Summary

K053028

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General Company Information

Name TechDevice Corporation

Address 650 Pleasant Street
Watertown, MA 02472

Contact: Leigh Hayward

Telephone: 617-972-5808

General Device Information

Product Name: TechDevice Guidewire

Common Name: Guidewire

Classification:
GCJ, Endoscope and Accessories 21 CFR 876. 1500

Predicate Devices

Guidewire K943737
Boston Scientific Corporation
Natick, MA 01760

Guidewire K935997
Boston Scientific Corporation
Natick, MA 01760

Guidewire K933334
Boston Scientific Corporation
Natick, MA 01760

Product Description:

The Guidewire is constructed of a stainless steel core wire and a stainless steel or 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 iridium marker bands may be placed under the coil to aid in visualization. Exit markers may be printed on the proximal section of the guidewire to aid the physician in determining the depth of insertion.

Indications for Use:
The TechDevice Guidewire facilitates placement and exchange of catheters and other instruments in the alimentary track. This device is not indicated for neuro, or cardiac use

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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

Conclusion:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 1 2006

Mr. Leigh Hayward
Director of Technical Operations
TechDevice Corporation
650 Pleasant Street
WATERTOWN MA 02472

Re: K053028
Trade/Device Name: TechDevice Guidewire
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KOG
Dated: December 22, 2005
Received: December 23, 2005

Dear Mr. Hayward:

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 (Premarket Approval), 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K053028

Device Name: TechDevice Guidewire

Indications For Use:

The TechDevice Guidewire facilitates placement and exchange of catheters and other instruments in the alimentary tract. This device is not indicated for neuro or cardiac use.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C) (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053028