NOV - 7 2005

K 052280

Section 5 — 510(k) Summary

(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)

5.1 General Provisions

Submitter's Name and Address	Boston Scientific Corporation 2011 Stierlin Court Mountain View, California 94043-4655
Contact Person	Debbie McIntire Senior Regulatory Affairs Specialist (650) 623-1703
Classification Name	Device, Coronary Saphenous Vein Bypass Graft, Temporary, For Embolization Protection
Common or Usual Name	Embolic Protection Guidewire
Proprietary Name	Boston Scientific FilterWire EZ™ Embolic Protection System
Manufacturing Facilities	Boston Scientific Corporation 2011 Stierlin Court Mountain View, California 94043-4655

5.2 Name of Predicate Device

Boston Scientific FilterWire EZ Embolic Protection System (K032884)

5.3 Device Description

The Boston Scientific FilterWire EZ Embolic Protection System is a temporary intra-vascular 0.014" guide wire filtration system that is placed distal to the vessel lesion to be treated by interventional procedures. The system consists of a protection wire in 190 and 300 cm lengths, an EZ Delivery Sheath, an EZ Soft Tip Retrieval Sheath and accessories. A separately packaged EZ Bent Tip Retrieval Sheath will also be available as an alternate tool for retrieving the FilterWire EZ protection wire. The 190 cm wire is compatible with the Boston Scientific extension wire (K970376 cleared June 6, 1997) for over-the-wire catheter exchanges.

The FilterWire EZ protection wire is delivered through a low profile delivery sheath, which allows free rotational movement of the guide wire component. The tip of the protection wire and the filter loop are radiopaque. The filter is deployed distal to the lesion, and the delivery sheath removed, leaving only the filter and filter loop at the end of a standard 0.014" guide wire. Interventional devices, which are 0.014" guide wire compatible, may then be tracked over the FilterWire guide wire to treat the lesion.

After treating the lesion, all interventional devices are removed, and a retrieval sheath is advanced to collapse the filter loop, trapping any emboli caught during the procedure. The retrieval sheath and FilterWire are then removed from the patient simultaneously.

5.4 Intended Use

The FilterWire EZ Embolic Protection System is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/ debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.5 to 5.5 mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.

5.5 Summary of Labeling Change

The FilterWire EZ™ Embolic Protection System Directions for Use insert includes two new statements under the Contraindications section which are added to the presently commercialized Directions for Use. These statements contraindicate FilterWire EZ use in patients with severe allergy to heparin and in patients with bleeding diathesis or other disorders which limit the use of anticoagulant therapy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 2005

Boston Scientific Corporation
c/o Ms. Debbie McIntire
Senior Regulatory Affairs Specialist
2011 Stierlin Court
Mountain View, CA 94043-4655

Re: K052280
FilterWire EZ™ Embolic Protection System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: NFA
Dated: September 30, 2005
Received: October 3, 2005

Dear Ms. Brinza:

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,

Donna R. Lachman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 — Indications for Use Statement

510(k) Number (if known): K052280

Device Name: FilterWire EZ™ Embolic Protection System

Indications for Use:

The FilterWire EZ Embolic Protection System is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/ debris) while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.5 to 5.5 mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid or peripheral vasculature.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

10/25/05

510(k) Number K052280