K061332

AUG 11 2006

Section 5 510(k) Summary

"510(k) Summary" as required by section 807.92(c)

5.1 General Provisions

Submitter's Name and Address	Boston Scientific Corporation 2011 Stierlin Court Mountain View, CA 94043-4655, U.S.A.
Contact Person	Debbie McIntire Senior Regulatory Affairs Specialist Tel: (650) 623-1703 Fax: (650) 623-1610
Classification Name	21CFR870.1250, Percutaneous Catheter
Common or Usual Name	Distal embolic protection guide wire
Proprietary Name	Boston Scientific FilterWire EZ Embolic Protection System
Manufacturing Facilities	Boston Scientific Corporation 2011 Stierlin Court Mountain View, CA 94043-4655, U.S.A.

5.2 Name of Predicate Device

The Boston Scientific FilterWire EZ Embolic Protection System (2.25 mm – 3.5 mm) is substantially equivalent in design and intended use to the FilterWire EZ Embolic Protection System (2.25 mm – 3.5 mm) cleared under K051984.

5.3 Device Description

The subject FilterWire EZ Embolic Protection System (2.25 mm – 3.5 mm) consists of the same four main components as the FilterWire EZ Embolic Protection System (2.25 mm – 3.5 mm) cleared under K051984. These components are:

- A Protection Wire (0.014 in. [0.36 mm] guide wire and integrated filter loop) that incorporates a circular/oval-shaped structure (filter loop assembly), which supports a thin, porous, filter membrane designed to contain and remove embolic material while maintaining blood flow.
- An EZ Delivery Sheath, a low-profile sheath that constrains the filter on the protection wire for delivery to the site of filter loop placement. It is pre-packaged with the protection wire for coaxial delivery and has a slit for easy removal in a peel-away fashion.
- An EZ Retrieval Sheath is intended to negotiate through the anatomy over the protection wire to retrieve the filter. The sheath is designed to track easily to the filter without catching on obstacles such as stents. The sheath has a radiopaque marker and is silicone coated.
- A tool kit containing one peel-away introducer, one wire torquer and one hemostasis valve dilator

5.4 Intended Use

The FilterWire EZ Embolic Protection System* is indicated for use as a guide wire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in coronary saphenous vein bypass grafts. The diameter of the artery at the site of filter loop placement should be between 2.25 mm and 5.5 mm.

The safety and effectiveness of this device as an embolic protection system has not been established in cerebral, carotid and peripheral vasculature or in treating native coronaries, including acute myocardial infarction.

5.5 Summary of Technological Characteristics

The FilterWire EZ Embolic Protection System (2.25 mm – 3.5 mm) indicated for use in saphenous vein bypass grafts is equivalent to the FilterWire EZ Embolic Protection System (2.25 mm – 3.5 mm) cleared under K051984 in that the intended use, principles of operation, design and materials are similar. The following design attributes are the same or similar for the subject device and the predicate device:

Design Attributes
Single Operator Exchange delivery systems
Filter-based technology
Nitinol® filter/basket component
Bionate™ polyurethane filter membrane

* The FilterWire EZ Embolic Protection System (2.25 mm – 3.5 mm) is an extension of the FilterWire EZ Embolic Protection System family (sizes 3.5 mm – 5.5 mm) cleared under K032884 and K052880; the indications for use in the combined directions for use (for the FilterWire EZ family) will reference the entire vessel diameter range of 2.25 mm to 5.5 mm.

Compatibility with .014 in. guide wires
Compatibility with 6F guide catheters
Available in 2 wire lengths; 190 cm and 300 cm
Radiopaque guide wire tips
Radiopaque markers on filter loop

5.6 Non-Clinical Performance Data

Where appropriate, testing conformed to the requirements of 21 CFR Part 58, Good Laboratory Practices (GLP). Specifically, non-clinical tests conducted for the FilterWire EZ Embolic Protection System (2.25 mm – 3.5 mm) showed the device met its design-input criteria, and is safe and effective for its intended use.

5.7 Statement of Substantial Equivalence

Based on a comparison of design, fundamental technology, intended use, results of in-vitro testing, in-vivo testing, biocompatibility, and packaging, Boston Scientific considers the FilterWire EZ Embolic Protection System (2.25 mm – 3.5 mm) to be substantially equivalent to the FilterWire EZ Embolic Protection System (2.25 mm – 3.5 mm) (K051984).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1 2006

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

Re: K061332
Trade/Device Name: FilterWire EZ Embolic Protection System (2.25mm – 3.5mm)
Regulation Number: 21 CFR 870.1250
Regulation Name: Distal Embolic Protection Guidewire
Regulatory Class: Class II
Product Code: NFA
Dated: August 4, 2006
Received: August 4, 2006

Dear Ms. McIntire:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Section 3 — Indications For Use

Device Name: FilterWire EZ™ Embolic Protection System

Indications for Use:

The indications for use for the FilterWire EZ Embolic Protection System are as follows:

The FilterWire EZ Embolic Protection System is indicated for use as a guide wire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in coronary saphenous vein bypass grafts. The diameter of the artery at the site of filter loop placement should be between 2.25 mm and 5.5 mm.

The safety and effectiveness of this device as an embolic protection system has not been established in cerebral, carotid and peripheral vasculature or in treating native coronaries, including acute myocardial infarction.

Prescription Use____X____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (Per 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 K061332