K032884

AUG - 6 2004

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 EX Embolic Protection System (K023691)

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 Technological Characteristics

The FilterWire EZ protection wire is built on current guide wire technology. Using a standard guide wire as the foundation, a filter bag located approximately 6 cm proximal to the distal tip of the guide wire is deployed distal to the lesion to be treated. The FilterWire EZ protection wire is retracted into the 1.1 mm outer diameter EZ Delivery Sheath and the assembly is inserted and advanced through a 6F minimum coronary guiding catheter. The sheathed FilterWire is advanced across the target lesion. Filter deployment is accomplished by holding the FilterWire EZ protection wire steady while pulling back the EZ Delivery Sheath. When unsheathed, the Nitnol filter loop opens and apposes the vessel wall. Once the filter loop expands, the blood flows through the polyurethane filter bag. The filter bag utilizes laser-drilled holes measuring approximately 110 microns in diameter. The filter bag acts as a strainer, capturing debris while allowing uninterrupted blood flow distally. While the FilterWire EZ protection wire is deployed, stent and/or angioplasty catheters are threaded over the protection wire from treatment of the vessel. While the filter is deployed, the physician monitors blood flow angiographically. Upon completion of the intervention, the device can be withdrawn into the EZ Soft Tip Retrieval Sheath or if needed, by the EZ Bent Tip Retrieval Sheath. As the filter retraction is initiated, the filter loop closes, trapping embolic debris inside the filter bag. The sheathed filter can then be removed through the vessel and into the guiding catheter.

The FilterWire EZ Embolic Protection System is intended for deployment of the filter loop in saphenous vein grafts with inner diameters of 3.5 to 5.5mm. The FilterWire EZ Embolic Protection System is similar to the predicate device in that both devices employ distal embolic protection filters using 110-micron diameter holes and both devices are 0.014" diameter guide wire platforms. The FilterWire EZ Embolic Protection System provides a slightly smaller sheathed profile for delivery than the predicate (1.1 mm vs., 1.3 mm) and the filter loop attachment design has been changed to allow the guide wire to pass through the filter loop instead of on the side of the filter loop.

The primary design differences between the FilterWire EX System and the FilterWire EZ Embolic Protection System are:

The FilterWire EZ Protection Wire

- Employs a suspended loop design to ensure apposition and capture efficiency in both straight and curved vessel segments. The guidwire passes through the filter loop and the support arm connects to the loop.
- Has downsized several components in order to fit inside a reduced profile delivery sheath.
- Incorporates a silicone coating of the distal portion of the protection wire and distal portion of the delivery sheath to reduce sheathing and unsheathing forces.
- Eliminates in-house soldering operations on certain components. These components were re-designed to incorporate a bonding process.

The EZ Delivery Sheath

- Is designed for use as an over-the-wire sheath during device delivery to improve wire control.
- Incorporates a slit to allow for a rapid exchange after device deployment (peel-away configuration).
- Employs a shortened tapered core wire and adds a silicone coating to the distal tip to facilitate deployment.
- Eliminates the distal marker band to provide a lower sheath profile.
- Facilitates device preparation by pre-loading the FilterWire EZ protection wire inside the EZ Delivery Sheath.

The EZ Soft Tip and EZ Bent Tip Retrieval Sheaths

- Moves the internal stop location to accommodate the Filter loop design.

5.6 Non-Clinical and Clinical Test Summary

Non-Clinical:
In-vitro testing consisted of dimensional testing, tensile/torque testing and functional testing. Biocompatibility, packaging testing, product shelf life testing and functional testing in animal models have also been successfully conducted. Test results verified that the FilterWire EZ Embolic Protection System met all applicable product specifications and is deemed adequate for its intended use.

Clinical:
BLAZE was a prospective, multi-center, non-randomized study. Ninety (90) registry patients from 16 U.S. sites and 6 European sites were enrolled and treated. Clinical data from European and US study sites were pooled. There were no statistically significant differences in the important demographic or angiographic variables between patients from the two geographic regions, i.e. age, gender, baseline QCA, and final QCA.

This study was performed to assess the safety and performance of the FilterWire EZ System during percutaneous treatment of saphenous vein graft stenosis. The primary endpoint of this study was Major Adverse Cardiac Events (MACE) at 30 days post procedure. Secondary endpoints included MACE during index hospitalization, device success, clinical success, and final TIMI flow. After the procedure there was no standard anticoagulation regimen but patients who were treated with stents were to receive Clopidogrel (75 mg daily) or Ticlopidine (250 mg b.i.d.) for 30 days and Aspirin (325 mg daily) for at least 6 months. Follow-up at 30 days was completed. No further follow-up was required per protocol.

FIRE was a prospective multi-center, randomized, two-arm, controlled trial that utilized a hybrid design combining a superiority trial comparing FilterWire EX to a conventional guide wire with no protection, and a non-inferiority trial comparing FilterWire EX to the Medtronic® AVE PercuSurge GuardWire Plus. A total of eight hundred sixty-four (864) patients from 62 U.S. sites and 4 Canadian sites were enrolled. The FIRE trial was performed to establish the safety and efficacy of treatment with the Boston Scientific FilterWire EX device during angioplasty/stenting of saphenous vein grafts. The FIRE trial was originally designed as a prospective, randomized, controlled trial comparing FilterWire to no protection. During the course of the trial, the PercuSurge GuardWire Plus® device became commercially available. At this point, a "Hybrid Trial" was conceived to create two separate trial arms – the original arm (for randomization to no protection) and an arm for randomization to the GuardWire Plus device. Two hundred thirteen (213) patients were enrolled and randomized to no protection. A total of six hundred fifty-one (651) patients were randomized to the commercially available GuardWire Plus device.

The primary endpoint of the FIRE trial was MACE at 30 days post procedure. Secondary safety endpoints were CK and CK-MB post procedure, target vessel

failure at 6 months and MACE during index hospitalization. Secondary efficacy endpoints were device success, clinical success and final TIMI flow. After the procedure all patients were to be treated with Aspirin (325 mg daily) indefinitely. There was no other prescribed anticoagulation regimen but patients who were treated with stents were to receive Clopidogrel (75 mg daily) or Ticlopidine (250 mg b.i.d.) for 30 days. Follow-up at 30 days and 6 months was completed.

Methods from the BLAZE study were analogous to the previously completed randomized FIRE Trial (FilterWire EX) with respect to enrollment criteria and primary endpoint, with the notable exception that FilterWire EZ placement within straight and curved vessel segments was allowed. In addition, patient demographics and baseline angiographic characteristics were largely comparable. Ninety (90) registry patients with diseased saphenous vein grafts were enrolled and treated using the FilterWire EZ Embolic Protection System. The 30-day MACE rate observed for the FilterWire EZ device in the BLAZE Study was 6.7%. This 30-day MACE rate compares favorably to the historical control 30-day MACE rate observed for the FilterWire EX device in the FIRE trial which was 9.9% (Difference of 3.3% [95% C.I. -2.8%, 9.3%)].

Boston Scientific Corporation considers the FilterWire EZ Embolic Protection System substantially equivalent to the FilterWire EX Embolic Protection System legally marketed by Boston Scientific Corporation based on a comparison of intended use and the results of *in-vitro* testing, *in-vivo* testing and clinical evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2004

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

Re: K032884
Trade Name: FilterWire EZ™ Embolic Protection System
Regulation Number: 21 CFR 870.1250
Regulation Name: Distal Embolic Protection Guidewire
Regulatory Class: Class II (two)
Product Code: NFA
Dated: May 7, 2004
Received: May 10, 2004

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 (301) 594-4646. 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/dsma/dsmamain.html

Sincerely yours,

Donna R Vichner

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

Enclosure

510(k) Number – K032884

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____ or Over-the-Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Mahnen

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032884