JUN 8 - 2005

K051179

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	Catherine A. Peters Regulatory Affairs Specialist Tel: (650) 623-1755 Fax: (650) 623-1610
Classification Name	21 CFR 870.1250, Percutaneous Catheter
Common or Usual Name	Retrieval Sheath
Proprietary Name	Boston Scientific EZ Plus Retrieval Sheath
Manufacturing Facilities	Boston Scientific Corporation 2011 Stierlin Court Mountain View, CA 94043-4655, U.S.A.

5.2 Name of Predicate Device

Boston Scientific FilterWire EZ Embolic Protection System, (K032884)

5.3 Device Description

The Boston Scientific EZ Plus Retrieval Sheath, a separately packaged, accessory component of the Boston Scientific FilterWire EZ Embolic Protection System, is an easy exchange sheath with a retractable tip at the distal end. The retractable tip facilitates its ability to cross a deployed stent as well as to negotiate tortuous anatomy when retrieving the FilterWire EZ protection wire. The radiopaque retractable tip and marker band at the distal end of the EZ Plus Retrieval Sheath provide visualization of the device under fluoroscopic imaging. At the completion of the procedure, the EZ Plus Retrieval Sheath is advanced up the FilterWire to just proximal the deployed filter loop. The filter is resheathed into the distal end of the EZ Plus Retrieval Sheath and the entire system is then removed from the patient.

5.4 Intended Use

The EZ Plus Retrieval Sheath is indicated for use with the Boston Scientific FilterWire EZ™ Embolic Protection System as an alternative method for retrieval and/or redeployment of a deployed FilterWire EZ device. Reference the FilterWire EZ Embolic Protection System Instructions for Use for indications, warnings and precautions for the system (see Appendix 2).

5.5 Summary of Technological Characteristics

The Boston Scientific EZ Plus Retrieval Sheath ("EZ Plus") is an accessory component to the FilterWire EZ Embolic Protection System cleared under K032884. The EZ Plus, built on core retrieval sheath technology, is an easy exchange sheath with a retractable tip at the distal end. The EZ Plus tip assembly is connected to a retractable thumb piece via a retraction wire.

The radiopaque retractable tip and marker band at the distal end provide visualization of the device under fluoroscopic imaging. At the completion of a procedure using the FilterWire EZ Embolic Protection System, the EZ Plus Retrieval Sheath is advanced over the FilterWire EZ protection wire, and the EZ Plus tip is retracted, providing access to a cavity which is used to retrieve the filter. The filter is then re-sheathed into the distal end of the EZ Plus Retrieval Sheath. As the filter retraction is initiated, the filter loop closes, trapping embolic debris inside the filter. The entire system is then removed from the patient.

With the addition of the EZ Plus Retrieval Sheath as an accessory component, the indications for use for the FilterWire EZ Embolic Protection System cleared under K032884 have not changed. Like the EZ Soft Tip and Bent Tip Retrieval Sheaths currently cleared under K032884, the EZ Plus Retrieval Sheath is intended for retrieval of a deployed FilterWire EZ protection wire. Also, like the EZ Soft Tip Retrieval Sheath, the EZ Plus Retrieval Sheath may be used for repositioning/redeployment during a procedure.

5.6 Non-Clinical Test Summary

Where appropriate, testing conformed to the requirements of 21 CFR Part 58 [Good Laboratory Practices (GLP)]. Specifically, non-clinical tests conducted for the EZ Plus Retrieval Sheath showed the device met its design-input criteria, and is 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

JUN 8 - 2005

Boston Scientific Corporation
c/o Ms. Catherine A. Peters
Regulatory Affairs Specialist
2011 Stielin Court
Mountain View, CA 94043-4655

Re: K051179
Trade/Device Name: EZ Plus Retrieval Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: NFA
Dated: May 5, 2005
Received: May 9, 2005

Dear Ms. Peters:

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,

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

Enclosure

K051179

Section 3 — Indications For Use

Device Name: Boston Scientific EZ Plus Retrieval Sheath

Indications for Use:

The indications for use for the EZ Plus Retrieval Sheath are as follows:

The EZ Plus Retrieval Sheath is indicated for use with the Boston Scientific FilterWire EZ™ Embolic Protection System as an alternative method for retrieval and/or redeployment of a deployed FilterWire EZ device.

Reference the FilterWire EZ Embolic Protection System Instructions for Use for indications, warnings and precautions for the system.

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)

[signature]

(Division Sign-Off)
Division of Cardiovascular Devices

(Division Sign-Off) Division Number K051179