IX. 510(k) Summary of Safety and Effectiveness

MAR 1 2 2002

SUBMITTER:

Boston Scientific Target
47900 Bayside Parkway
Fremont, CA 94538

CONTACT PERSON:

Seth A. Schulman
TEL: 510-440-7753
FAX: 510-440-7752
E-MAIL: schulmas@bsci.com

DATE PREPARED: December 7, 2001

CLASSIFICATION NAME: Retrieval Device
(21 CFR Section 870.1250)

COMMON NAME: Retrieval Device

PROPRIETARY NAME: In-Time™ Retrieval Device

PREDICATE DEVICE: Retriever™-18 Endovascular Snare (K914067)

DEVICE DESCRIPTION: The In-Time™ Retrieval Device consists of a braided catheter shaft, with a radiopaque basket attached to the distal tip of the catheter. The inner lumen of the catheter contains a flexible, guiding corewire, which is tapered from the proximal to distal end.

The corewire extends distally 3 cm from the basket and is not removable from the catheter. The corewire can be rotated freely as well as moved distally and proximally within the catheter approximately 1.5 cm. The 3 cm radiopaque distal coil extending from the basket facilitates fluoroscopic visualization.

A luer fitting is located on the catheter hub and is used for the attachment of accessories and to facilitate the continuous flush of solution.

The catheter shaft is coated with HYDROLENE™, a hydrophilic coating that reduces friction during manipulation in a guide catheter and in blood vessels.

The In-Time™ Retrieval Device is designed to be used with a guide catheter.
The In-Time™ Retrieval Device can be used in vessel diameters ranging from 2 mm to 4 mm.

Each In-Time™ Retrieval Device is packaged with the following accessory items: catheter introducer, shaping mandrel, torquer and Rotating Hemostatic Valve (RHV). The items are sealed in a sterile pouch located within the larger pouch.

INTENDED USE:

The In-Time™ Retrieval Device is designed for use with a guiding catheter for the retrieval of intravascular foreign objects such as coils, balloons, portions of catheters and / or loop wires misplaced during interventional radiologic procedures in peripheral, neuro and cardiovasculature.

MATERIALS:

All component materials of the In-Time™ Retreival Device are biocompatible in accordance with ISO 10993-1.

TECHNOLOGICAL CHARACTERISTICS COMPARISON:

Verification Test Summary Table:
Predicate Retriever™-18 Endovascular Snare vs In-Time™ Retrieval Device

Test or Point of Comparison	In-Time™ Retrieval Device
Biocompatibility	Meets acceptance criteria established by ISO 10993-1.
Dimensional Tests	Meets acceptance criteria established for device.
Friction	Meets acceptance criteria established for predicate device.
Foreign Body Removal	Meets acceptance criteria established for predicate device.
Sterilization	Meets acceptance criteria established for predicate device.

Verification Test Summary Table:
In-Time™ Retrieval Device

Functional Test	In-Time™ Retrieval Device
Tensile	Meets acceptance criteria established for device.
Rotation	Meets acceptance criteria established for device.
Tip Buckling	Meets acceptance criteria established for device.
Turns to Failure	Meets acceptance criteria established for device.
Basket Activation Force	Meets acceptance criteria established for device.
Basket Closing Force	Meets acceptance criteria established for device.
Surface Roughness	Meets acceptance criteria established for device.
Particulate Test	Meets acceptance criteria established for device.
Withdrawal Force from Catheter	Meets acceptance criteria established for device.

Conclusion:

The In-Time™ Retreival Device is substantially equivalent to the predicate Retriever™-18 Endovascular Snare with regards to safety and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2002

Mr. Seth A. Schulman
Senior Regulatory Affairs Specialist
Boston Scientific/Target
47900 Bayside Parkway
Fremont, California 94538

Re: K014109
Trade/Device Name: In-Time™ Retrieval Device
Regulation Number: 870.5150
Regulation Name: Percutaneous retrieval device
Regulatory Class: II
Product Code: MMX
Dated: December 7, 2001
Received: December 14, 2001

Dear Mr. Schulman:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K014109

Name: In-Time™ Retrieval Device

Indications For Use:

The In-Time™ Retrieval Device is designed for use with a guiding catheter for the retrieval of intravascular foreign objects such as coils, balloons, portions of catheters and / or loop wires misplaced during interventional radiologic procedures in peripheral, neuro and cardiovasculature.

In-Time™ 4 and 6 strand / Guiding Catheter Selection Guide

In-Time™ Model	*In-Time™ Outer Diameter*	*Minimum Guiding Catheter Internal Diameter*
4 strand	3.0 F	6 F
6 strand	3.0 F	6 F

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use:_____
(Per 21 CFR §801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014109