

Section 4: Summary of Safety and Effectiveness**510(k) Summary****(Pursuant to Section 12 of the SAFE MEDICAL DEVICES ACT of 1990 and 21CFR807.92)**

Date Prepared: September 20, 1999

I. General Provisions

Submitter's Name and Address	Boston Scientific/Target 47900 Bayside Parkway Fremont, California 94538-6515
Contact Person	Gowan Lee Phone: (510) 440-7614 Fax: (510) 440-7752 E-mail: leeg@bsci.com
Classification Name	Catheter, Intravascular Occluding, Temporary (21CFR870.4450)
Product Code	MJN
Panel	Cardiovascular
Class	II
Common or Usual Name	Occlusion Balloon Catheter
Proprietary Name Catheter	Boston Scientific/Target Sentry™ Occlusion Balloon Catheter

II. Name of Predicate Devices

Predicate Devices for the Boston Scientific/Target Sentry Occlusion Balloon Catheter:

Boston Scientific/Target NDSB® (K895445, K921399, K950398, K960832)
 Boston Scientific/Medi-tech Occlusion Balloon Catheter (K781772)
 Boston Scientific/Target Hydrophilic FasTracker Infusion Catheter (K926243,
 K925813)
 Boston Scientific/Target TurboTracker Infusion Catheter (K960806)

III. Device Description

The Sentry Occlusion Balloon Catheter consists of an over-the-wire catheter with a soft compliant balloon attached at the distal end. Radiopaque markers (located at the proximal and distal ends of the balloon) facilitate fluoroscopic visualization. The Sentry Occlusion Balloon Catheter has a single lumen shaft that is used with the 510(k) cleared Boston Scientific/Target Transend-010 guidewire (K964611) hydrophilic 0.010" guidewire) to occlude the distal segment of the central lumen and allow inflation of the

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balloon. To facilitate sealing of the central lumen for balloon inflation, the guidewire is advanced slightly beyond the distal tip of the catheter where the distal seal is located. There is a slight increase in resistance as the guidewire passes through the distal seal, and at this point the balloon can be inflated. The guidewire can be moved distally or proximally once beyond the distal tip (seal portion) of the catheter and still maintain a positive seal for inflating the balloon.

The Sentry Occlusion Balloon Catheter has a HYDROLENE® hydrophilic exterior coating that reduces friction during manipulation. The device is manufactured in two sizes, one with a balloon length of 10 mm (nominal inflation diameter of 3.5 mm) and the other with a balloon length of 15 mm (nominal inflation diameter of 3.5 mm).

The catheter portion of the device utilizes the construction of the 510(k) cleared Boston Scientific/Target FasTracker Infusion Catheter (K926243, K925813) and the Boston Scientific/Target Turbo Tracker Infusion Catheter (K960806). This construction provides a flexible and strong catheter shaft which facilitates tracking through tortuous vasculature and accessing the target vessel.

IV. Intended Use

The Sentry Occlusion Balloon Catheter is intended for temporary intravascular occlusion. This device is not intended for use in the coronary arteries. This device is also not intended for use in the neurovasculature.

V. Testing in Support of Substantial Equivalence Determination

Substantial equivalence is based on the fact that the Sentry Occlusion Balloon Catheter has similar technological characteristics and intended use as the predicate devices. The Sentry Occlusion Balloon Catheter has been evaluated through a series of in vitro functional tests and biocompatibility studies. The functional tests that have been conducted are:

- visual
- dimensional
- cyclic fatigue
- rupture volume and balloon bond integrity
- balloon profile and compliance
- balloon deflation time
- balloon preparation
- initial peak inflation
- prox/mid junction tensile testing
- hub/shaft tensile testing
- radiopacity of markers
- guidewire compatibility
- chemical compatibility
- tip stiffness test

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The results of the functional testing and additional tests on biocompatibility, shelf life, and sterilization support substantial equivalence to the predicate devices. Results of these tests, in conjunction with the substantial equivalence claims as outlined in the premarket notification, demonstrate that the Sentry Occlusion Balloon Catheter is substantially equivalent to the predicate devices.

VI. Summary of Technological Characteristics Compared to the Predicate Device

The comparison of the subject device to the predicate devices shows technological differences in dimensions, materials, and construction. The noted differences are:

- The balloon material of the Sentry Occlusion Balloon Catheter is Thermoplastic Elastomer (TPE) (synthetic rubber), while Boston Scientific/Target Occlusion Balloon (K960832) and the Boston Scientific/Meditech Occlusion Balloon (K781772) are latex rubber elastomer.
- The Sentry Occlusion Balloon Catheter has an inflated balloon diameter of 2.5 mm – 4.0 mm. This specification falls below the lowest specification of 5.0 mm – 10.0 mm for the NDSB. With a smaller inflated balloon diameter, the Sentry Occlusion Balloon Catheter can be used in distal branches of the peripheral vasculature such as the popliteal artery, hepatic vessels, and mesenteric arteries.
- The specifications for tip extension on the Sentry Occlusion Balloon Catheter falls between 0 cm – 6 cm while the predicate devices have a specification of 0 cm – 4 cm. Although the overall length of the catheter remains within the parameters of the predicate devices, the specification for the tip of the subject device is longer by 2 cm.
- The Sentry Occlusion Balloon Catheter is different in construction than the predicate devices because it is an over-the-wire catheter. It is delivered over a guidewire that assists in delivery through tortuous vessels and also functions to seal the distal tip for balloon inflation. The predicate devices have sealed distal tips that do not allow the devices to track over a guidewire.

For these differences, functional and biocompatibility testing has been conducted on the Sentry Occlusion Balloon Catheter to demonstrate that these technological differences raise no new questions of safety and effectiveness. Other than these differences, all other aspects of the subject device are equivalent to, or fall within the specification ranges of the predicate devices.



MAR 23 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Gowan Lee
Boston Scientific/Target
47900 Bayside Parkway
Fremont, CA 94538

Re: K993292
Sentry Occlusion Balloon Catheter
Regulatory Class: II (Two)
Product Code: MJN
Dated: January 27, 2000
Received: February 9, 2000

Dear Mr. Lee:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



James E. Dillard III
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2: Indications for Use

510(k) Number: _____

Device Name: Sentry Occlusion Balloon Catheter

Indications for Use:

The Boston Scientific/Target Sentry Occlusion Balloon Catheter is intended for temporary intravascular occlusion. This device is not intended for use in coronary arteries. This device is not intended for use in the neurovasculature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over The Counter Use _____

Christopher M. Ahner for Dillard

(Division Sign-Off)

Boston Scientific/Target 510(k)
Sentry Occlusion Balloon Catheter
Confidential

Division of Cardiovascular, Respiratory,
and Neurological Devices

September 22, 1999
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