

510(k) Summary Of Safety And Effectiveness (cont.)

Legally Marketed Predicate Devices:

| Reference (Clearance Date) | Device |
|----------------------------|---|
| K002181 (11 Aug 2000) | GDC 10-UltraSoft® Coils (introduction of UltraSoft coils) |
| K021494 (6 June 2002) | GDC Power Supply and Detachable Coil Connecting Cables |
| K031049 (3 June 2003) | Clearance of ISAT indication for all GDC devices |
| K042539 (19 Oct 2004) | GDC 360 Detachable Coils (introduction of 360 shape coils) |
| K050700 (15 April 2005) | Matrix ² ® Detachable Coils |
| K093142 (4 Feb 2010) | Target Detachable Coil and InZone® Detachment System |

Device Description:

Boston Scientific Corporation's **Target Detachable Coils** are comprised of four coil types: **Target Coil 360 STANDARD**, **Target Coil 360 SOFT**, **Target Coil 360 ULTRA** and **Target Coil HELICAL ULTRA**. All Target Coils are stretch resistant coils. Target Coils incorporate a length of multi-strand material through the center of the coil designed to help resist stretching. Target Coils are designed for use with Boston Scientific's InZone™ Detachment System (sold separately).

Each Target Coil type consists of a platinum-tungsten alloy coil attached to a stainless steel delivery wire. For Target Coil 360 STANDARD, Target Coil 360 SOFT and Target Coil 360 ULTRA coils the distal end of the main coil is formed such that there is a smaller distal loop at the end of the main coil to facilitate placement of the coil. The diameter of the distal loop is 75% that of the rest of the main coil loops.

Boston Scientific's InZone Detachment System is intended for use with all Boston Scientific Detachable Coils in the embolization of intracranial aneurysms and other vascular malformations of the neuro and peripheral vasculature.

On September 15, 2010 Boston Scientific submitted a Special 510(k) for modification of the grade of stainless-steel for two components of the finished device: 1) the stainless-steel wire sub-assembly and 2) the etched link component.

510(k) Summary Of Safety And Effectiveness (cont.)

Device Description:
(cont.)

The stainless-steel wire sub-assembly is a component of the delivery wire to which the main coil is attached. During assembly, the wire is placed coaxially through the lumen of a coil-hypotube assembly. The etched link component joins the delivery wire to the main coil.

The modification was made to minimize magnetic resonance imaging (MRI) artifact during follow-up MRI.

Verification Testing:

Verification testing of the modified Target Detachable Coil consisted of the following:

1) Functional testing to assess:

Main Junction Tensile Strength
Delivery Wire Tensile Strength
Coil Detachment Time

2) MR Compatibility testing to assess:

Magnetically induced displacement (ASTM F2052)
Magnetically induced torque (ASTM 2213)
Magnetically induced heating effect (in 1.5 T and 3 T MR systems - ASTM F2182)
MR induced image artifact (ASTM F2119)

As a result of MR compatibility testing, the Directions for Use (DFU) for the Target Detachable Coil has been revised to include a more comprehensive MR Conditional statement describing the conditions under which the device was tested.

3) Pre-clinical testing to provide post-implant MR artifact data and to assess and compare the modified Target Detachable Coil to control coils in coiled aneurysm models.

4) Confirmatory biocompatibility testing as follows:

MEM Elution Cytotoxicity
Hemolysis, Direct Contact
USP Physico-Chemical <661>

5) Assessment of the new grade stainless-steel by Boston Scientific's Corporate Toxicology group.

510(k) Summary Of Safety And Effectiveness (cont.)

- Accessories:** Target Detachable Coils are packaged within a flushing dispenser coil assembly. The dispenser coil is an accessory item with an attached flushport used to hydrate the coil prior to use.
- Indications for Use / Intended Use:** Target Detachable Coils are intended for use in the treatment of intracranial aneurysms and other neuro and peripheral vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.
- Target Coils are indicated for endovascular embolization of:
- Intracranial aneurysms
 - Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
 - Arterial and venous embolizations in the peripheral vasculature

Comparison to Predicate Device:

Target Detachable Coils

Boston Scientific Corporation's modified Target Detachable Coils have the same intended use/indications for use as the predicate Target Detachable Coils.

Although the coils incorporate modifications to materials and instructions for use, the modifications do not alter the fundamental scientific technology of the predicate devices.

Risk assessment of the modifications in the form of design and use failure modes and effects analysis (design and use FMEAs) has been conducted in accordance with EN ISO 14971 +A1:2003. Boston Scientific has determined the modifications to the predicate devices raise no new questions of safety or effectiveness.

Verification testing has demonstrated the modified Target Detachable Coils are substantially equivalent to the predicate Target Detachable Coils.

- Conclusion:** Because the subject modifications do not alter the intended use or indications for use of the predicate devices, or the fundamental scientific technology of the predicate devices; and because risk assessment of the modifications and successful verification testing raise no new questions of safety and effectiveness, Boston Scientific has determined the modified Target Detachable Coils to be substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Boston Scientific Neurovascular
c/o Mr. Jim Leathley
Regulatory Affairs Project Manager
47900 Bayside Parkway
Fremont, CA 94538-6515

OCT 15 2010

Re: K102672

Trade/Device Name: Target Detachable Coils
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: September 15, 2010
Received: September 16, 2010

Dear Mr. Leathley

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

OCT 15 2010

510(k) Number (if known): K102672

Device Name: Target Detachable Coils

Indications For Use:

Target Detachable Coils are indicated for the endovascular embolization of:

- Intracranial aneurysms
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
- Arterial and venous embolizations in the peripheral vasculature

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

D. Hoang
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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