K093142

Boston Scientific

FEB - 4 2010

510(k) Summary Of Safety And Effectiveness

Summary Date	October 1, 2009
Submitter Name and Address	Boston Scientific Corporation 47900 Bayside Parkway Fremont, CA. 94538
Contact Person:	Jim Leathley Regulatory Affairs Project Manager Phone: 510 440 7836 Fax: 510 440 7752 Email: leathlej@bsci.com
Trade Name:	Target® Detachable Coils InZone Detachment System
Common Name:	Occlusion Coil, Vascular Occlusion Coil, Neurovascular Occlusion Coil Power Supply
Classification Name:	Target Detachable Coils are classed as vascular and neurovascular embolization devices under 21 CFR 870.3300 (KRD) and 21 CFR 882.5950 (HCG), respectively, and are Class II devices (special controls). The special control for the devices is FDA's guidance document, *Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices* (issued 29 Dec 2004). The InZone Detachment System is intended for use with all currently marketed Boston Scientific Detachable Coils in the embolization of intracranial aneurysms and other vascular malformations of the neuro and peripheral vasculature.

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

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.

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.

There are no accessories to the InZone Detachment System.

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

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.

Comparison to Predicate Device:

Target Detachable Coils

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

Although the coils incorporate modifications in design, materials, packaging, 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 Target Detachable Coils are substantially equivalent to the current legally marketed predicate devices.

Comparison to Predicate Device (cont.):

InZone Detachment System

Boston Scientific Corporation's InZone Detachment System has the same intended use and indications for use as the current legally marketed predicate device, Boston Scientific's Detachable Coil Power Supply cleared under premarket notification K021494 (cleared 6 June 2002).

Although the InZone Detachment System incorporates modifications in materials, firmware, packaging, and instructions for use, the modifications do not alter the fundamental scientific technology of the predicate device.

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 device raise no new questions of safety or effectiveness.

Verification testing of the InZone Detachment System, including electrical safety testing in accordance with applicable parts of the EN 60601-series of standards, has demonstrated the devices to be substantially equivalent to the current legally marketed predicate device.

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 effectivenss, Boston Scientific has determined the Target Detachable Coils and InZone Detachment System to be substantially equivalent to the current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

FEB - 4 2010

James Leathley
Regulatory Affairs Project Manager
Boston Scientific Neurovascular
47900 Bayside Parkway
Fremont, CA 94538-6515

Re: K093142
Trade/Device Name: Target Detachable Coils and InZone Detachment System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: II
Product Code: HCG and KRD
Dated: January 22, 2010
Received: January 25, 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.

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" (21CFR 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

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 STATEMENT

510(k) Number: K093142

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

Device Name: InZone Detachment System

Intended Use:

The 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Kristen Bowsher
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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