K103008

510(k) Summary Of Safety And Effectiveness

DEC 10 2010

Summary Date October 8, 2010

Submitter Name and Address

Boston Scientific Corporation
47900 Bayside Parkway
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Contact Person:

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Trade Name: InZone™ Detachment System

Common Name: Power Supply

Classification Name: 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.

Boston Scientific's detachable coils are Class II devices (special controls) classed as neurovascular embolization devices under 21 CFR 882.5950 (HCG) and vascular embolization devices under 21 CFR 870.3300 (KRD).

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).

Legally Marketed Predicate Devices:

Reference (Clearance Date)	Device
K093142 (4 Feb 2010)	Target Detachable Coils and InZone Detachment System
K092666 (30 Sept 2009)	InZone Detachment System and IZDS Connecting Cable

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

Device Description:

Boston Scientific's InZone™ Detachment System is a sterile, handheld, single-patient use device designed for use with Boston Scientific Detachable Coils. The device consists of an enclosure with a detachment button, five LED indicator lamps, a funnel inset at its distal end, and a cable connection port. The device comes pre-loaded with two AAAA (1.5 VDC) batteries.

How the Device Functions

Use of Boston Scientific's detachable coils involves a minimally invasive procedure to access the treatment area (intracranial aneurysm or other neuro or peripheral abnormality) from within a blood vessel (endovascular therapy). Treatment involves insertion of a Boston Scientific two tip-marker microcatheter into a patient's femoral artery and then navigation of the microcatheter through the vascular system, into the neuro or peripheral vasculature, and then to the site of the lesion.

Detachable coils are used in conjunction with:

- Boston Scientific microcatheters
- a Boston Scientific InZone Detachment System
- a Boston Scientific IZDS Connecting Cable, and
- a Patient Return Electrode (an off-the-shelf 20 or 22 gauge stainless-steel hypodermic needle)

Microcatheters, InZone Detachment System and IZDS Connecting Cable are all sold separately.

During a procedure, a physician will assess the target lesion to determine the type, size and number of coils to use. After prepping the patient and preparing the coil according to the instructions for use, the coil is delivered through the microcatheter to the site of the lesion. The delivery wire enables the physician to deploy, position, or reposition the coil until proper placement. Prior to detachment of the coil, the entire device (i.e., coil and delivery wire) may be withdrawn completely, if necessary (e.g.,, if the physician desires to use a different size or shape coil).

The radiopaqueness of the platinum-tungsten coil, in conjunction with radiopaque markers on the coil's delivery wire and on the microcatheter, enable the physician to properly position the device within the lesion and to always know the location of the coil relative to the distal tip of the microcatheter.

After being placed at the site of the lesion, the coil is detached from its delivery wire through an electrolytic process using a Boston Scientific InZone Detachment System (**Table 1**).

Table 1 -
Compatibility between Boston Scientific's InZone Detachment System and Detachable Coils

	Types of Coils that can be used
InZone Detachment System (M00345100940)	GDC Detachable Coils[1] Matrix[2] Detachable Coils[1] Target Detachable Coils[2]

1 For coil detachment, requires use of Boston Scientific's IZDS Connecting Cable (M00345110250) with the InZone Detachment System (see K092666).

2 No cable required for coil detachment (see K093142).

When using the InZone Detachment System to detach GDC and Matrix[2] Detachable Coils:

An IZDS Connecting Cable is used in conjunction with an off-the-shelf patient return electrode. The IZDS Connecting Cable (Model / UPN M00345110250) is a 180 cm ground cable (black) for use with the *InZone Detachment System.* There are no accessories provided with the IZDS Connecting Cable.

The proximal end of the coil's delivery wire is inserted into the InZone Detachment System (anode connection), and the IZDS Connecting Cable completes the circuit between the InZone Detachment System ground port and the patient return electrode (cathode connection).

The InZone Detachment System and IZDS Connecting Cable are sold separately.

When using the InZone Detachment System to detach Target Detachable Coils:

No cable is required as the device's composite metal and polymer wire incorporates an anode and cathode into the wire thus eliminating the need to use a connecting cable and patient return electrode when detaching a Target Detachable Coil .

The proximal end of the coil's delivery wire is inserted into the InZone Detachment System (anode connection); the device's delivery wire hypotube provides the current return path (cathode connection).

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Scientific Concept

In the use of Boston Scientific Detachable Coils, detachment of the coil from its delivery wire is accomplished by means of an electrolytic process wherein the body's electrolytes serve as the electrolytic carrier between positive and negative electrodes. Since body fluids are relatively ionic, these fluids serve as good conductors for the minimal electric current generated by the InZone Detachment System. Boston Scientific's detachable coils are designed so that electrolytic dissolution occurs in a defined area called the detachment zone.

Operation of the InZone Detachment System in the detachment of coils is governed by the InZone device's firmware first detecting the type of delivery wire which is inserted into the units funnel.

When used with Boston Scientific's GDC or Matrix^2 Detachable Coils, the InZone Detachment System operates at a maximum 12VDC and a maximum current of 1.0 mA.

For Target Detachable Coils, when the InZone Detachment System detects that a Target Detachable Coil delivery wire has been inserted into the units funnel, the device's firmware engages circuitry which operates the device at a maximum 28VDC and 1.8 mA.

Physical and Performance Characteristics

Description:	Sterile, hand-held, internally powered, disposable unit, used within sterile field
Size:	14.0 x 5.8 x 2.8 cm (5.5 x 2.3 x 1.1 inch)
Weight:	80 g (2.8 oz)
Power:	3V
Power Source:	Two 1.5 V (AAAA) DC batteries (in series)
CPU Operating Voltage:	3.3 V DC
Max Current:	When detaching GDC and Matrix^2 Coils: 1mA When detaching Target Detachable Coils: 1.8 mA
Power Switch:	Inserting coil delivery wire turns unit on. Removing delivery wire turns unit off. Unit turns off after 2 minutes if unit detects no activity
Safety Features:	At start up: Memory integrity (checksum assessment); calibration validity During detachment: Over-current / over-voltage (at least 10x/sec) Software consistently running (at least 100x/sec)
Delivery Wire Interface:	InZone slides over proximal 6.5 cm of coil delivery wire
Attachment to Patient Return Electrode (PRE):	InZone slides over proximal 6.5 cm of coil delivery wire

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Physical and Performance Characteristics (cont.)

Cable Socket Type: When detaching GDC and Matrix^2 Coils: Black cable with minigrabber attached to PRE.
When detaching Target Detachable Coils: Not applicable; return is integral to the device.

Sterilization Method: Ethylene Oxide Gas
Sterile Barrier: PETG tray with Tyvek® lid
Packaging: Carton with Directions for Use
User Serviceable Parts: No user serviceable parts
User Required Maintenance: No user required maintenance
Calibration: Done at factory
Number of Detachments: Minimum of 20 detachments

User Interface / Displays:

Display	Comment/Action
Power	System Ready Indicator (LED) on and single audible tone when powered up
Current Voltage	Current Flow Indicator (LED) on (green) System Ready Indicator (LED) flashes (green) if high resistance detected
Cycle Complete	Cycle complete indicator (LED) on (green), 3 beeps
Running Low Battery Grounding	Current Flow Indicator (LED) on (green) Low battery Indicator (LED) flashes (amber) Grounding Indicator (LED) flashes (amber) until complete circuit is detected; when complete circuit is detected, LED remains steady on and System Ready indicator (LED) will turn on (green) accompanied by single beep
To start detachment Resume current after detachment	Press Detachment button Press Detachment button
Error	All 5 LEDs illuminate

Packaging: Each InZone Detachment System is packaged in a PETG tray; a Tyvek lid is heat-sealed to the tray. The tray with lid is then placed into a fiberboard carton along with Directions for Use.

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

Verification Testing:

Verification testing of the modified InZone Detachment System consisted of the following:

1) Funtional testing to assess proper operation of the InZone device at start-up and in the detachment of Boston Scientific Detachable Coils.

2) Software verification in accordance with Boston Scientific's Corporate SOP for Medical Device Software Development and in accordance with AAMI/ANSI/IEC 62304:2006, *Medical device software – Software life cycle processes.*

3) Risk assessment in accordance with EN ISO 14971:2009

4) Assessment of the modifications for impact upon:

Sterility Assurance (no impact)
Shelf Life (no impact)
Packaging Validation (no impact)
Compliance to standards

Accessories:

There are no accessories to the InZone Detachment System.

Indications for Use / 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.

Comparison to Predicate Device:

In October 2010 Boston Scientific submitted a Special 510(k) for modifications to device firmware to: a) reduce detachment cycle times; b) change the way the InZone unit signals detachment; and c) change the way the InZone device's grounding indicator signals proper grounding when the device is used with Boston Scientific GDC and Matrix2 Detachable Coils.

Additionally, the device's cone/wire guide component was modified to facilitate smoother placement of the InZone unit over detachable coil delivery wires.

Boston Scientific Corporation's modified InZone™ Detachment System has the same intended use and indications for use as the current legally marketed predicate device cleared under premarket notification K093142 (cleared 4 Feb 2010).

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

Comparison to Predicate Device (cont.):

Although the InZone Detachment System incorporates modifications to a device component, device firmware, packaging, and Directions 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 14971:2009. Boston Scientific has determined the modifications to the predicate device raise no new questions of safety or effectiveness.

Verification testing of the modified InZone Detachment System has demonstrated the device to be substantially equivalent to the predicate InZone Detachment System cleared under K093142.

Conclusion:

Since the subject modifications do not alter the intended use/ indications for use of the predicate device, or the fundamental scientific technology of the predicate device; 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 InZone Detachment System to be substantially equivalent to the current legally marketed predicate device cleared by FDA under K093142.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Boston Scientific Corporation
c/o Mr. James Leathley
Regulatory Affairs Project Manager
47900 Bayside Parkway
Freemont, CA 94538

DEC 10 2010

Re: K103008
Trade/Device Name: InZone™ Detachment System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG and KRD
Dated: November 9, 2010
Received: November 10, 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" (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/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 STATEMENT

510(k) Number: K103108

DEC 10 2010

Device Name: InZone™ Detachment System

Indications for Use:

Boston Scientific's InZone™ Detachment System is intended for use with all versions of BSC 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 √ 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

510(k) Number K103108