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Special 510(k): Boston Scientific Neurovascular's Matrix^2 Detachable Coils

Summary Of Safety And Effectiveness

Contact Person

Jim Leathley
Regulatory Affairs Project Manager
Boston Scientific Neurovascular
47900 Bayside Parkway
Fremont, CA. 94538

Trade Name

Matrix^2 Detachable Coil, Class II

Common Name

Occlusion Coil

Classification Name

Neurovascular Embolization Device (21 CFR Section 882.5950)

Predicate Devices

Number	Description	Predicate for	Clearance Date
K031168 (Boston Scientific Target)	Matrix Stretch Resistant Detachable Coils	Matrix^2 Stretch Resistant Coils: • Matrix^2 Helical UltraSoft SR • Matrix^2 2D Soft SR • Matrix^2 2D Standard SR • Matrix^2 Helical Soft SR • Matrix^2 360° UltraSoft SR • Matrix^2 360° Soft SR • Matrix^2 360° Standard SR	14 May 2003

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Number	Description	Predicate for	Clearance Date
K012985 (Boston Scientific Target)	Matrix Detachable Coils	Matrix^2 2D Firm Coils Matrix^2 3D Omega Coils • Matrix^2 3D Omega Standard • Matrix^2 Omega Firm	31 January 2002
K042539 (Boston Scientific Neuro-vascular)	GDC 360° Coils	Matrix^2 360° Coils: • Matrix^2 360° Standard • Matrix^2 360° Firm Matrix^2 360° Stretch Resistant Coils: • Matrix^2 360° UltraSoft SR • Matrix^2 360° Soft SR • Matrix^2 360° Standard SR	19 October 2004

Intended Use / Indications for Use

Matrix^2 Detachable Coils are intended for embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition - are considered by the treating neurosurgical team to be:

a) very high risk for management by traditional operative techniques, or,
b) inoperable,

and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature.

Matrix^2 Detachable Coils are also intended for arterial and venous embolizations in the peripheral vasculature.

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Device Description

Boston Scientific's detachable coil system consists of

- a detachable coil power supply (GDC Power Supply)
- an occlusion coil attached to a delivery wire (Matrix or GDC coil)
- a set of connecting cables for connecting the coil / delivery wire assembly to the power supply (GDC connecting cables)
- a patient return electrode
- two 9-volt batteries

each of which is sold separately.

The occlusion coil is detached by electrolytically dissolving a small portion of the delivery wire upon desired placement of the coil in the anatomy.

Electrolytically detachable occlusion coils are manufactured from platinum wire which is first wound into a primary coil and then formed into a secondary helical shape.

Coils are attached to a delivery wire, which consists of a ground stainless-steel core wire with a stainless-steel coil welded at the distal end and a Teflon® outer jacket. The delivery wire is similar to that employed for the predicate Matrix and Matrix SR devices cleared under K031168 and K012985.

The Detachable Coil Power Supply is a battery-operated, self-contained unit designed to initiate and control the electrolytic detachment of a coil inside an aneurysm.

Each time the power supply is turned on, the unit defaults to the 1.0 mA current setting. Pressing the "Current" switch one time changes the setting to the .05 mA current setting; pressing a second time changes the setting to 0.75 mA; pressing a third time returns the unit to the default 1.0 mA setting. Each time the switch is pressed, the current display flashes the new current setting.

The power supply is designed to apply a constant current through the GDC System and to detect when coil detachment has occurred. It maintains a constant current by:

1) sensing the amount of resistance to current flow through the detachable coil system, and
2) adjusting the voltage needed to maintain the desired current setting. It is also designed to identify subtle changes in the way current is flowing through the system and to recognize those changes which indicate detachment.

Once those patterns are identified, the power supply signals detachment and stops the flow of current through the system.

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Accessories Description

Accessories consist of the following:
- Two connecting cables, one black (274 cm long), the other red (152 cm long)
- Two standard 9 volt alkaline batteries

Technological Characteristics Comparison (to predicate devices)

Coil Dimensional Attributes

	Matrix^2 Detachable Coils
Coil Wire OD	Within the ranges of wire sizes used with predicate devices
Primary Coil OD	With the exception of one new primary coil size, all are within the range of primary coil OD for the predicate devices. No change to the OD of the primary coil + polymer which remains within the range of ODs for the predicate devices [see line item below for '*Primary Coil OD (platinu-tungsten wire + bioabsorbable polymer)*'
Secondary Coil OD	Expanded range of available sizes
Distal Tip Diameter (Stretch Resistant Coils only)	Larger distal tip diameters to accommodate new primary coil sizes
Primary Coil OD (platinu-tungsten wire + bioabsorbable polymer)	Within the range of primary coil OD (platinum-tungsten wire + bioabsorbable polymer) for predicate devices
Maximum Coil OD	Less than or equal to maximum coil OD for predicate devices
Delivery Wire Length	Same as for predicate devices
Delivery Wire Proximal OD	Same as for predicate devices
Delivery Wire Distal OD	Same as for predicate devices

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Technological Characteristics Comparison (cont.)

Materials

	Matrix^2 Detachable Coils
Main Coil	Same as predicate devices
Stretch Resistant Thread **(Matrix^2 Stretch Resistant Coils only)**	Same as predicate devices
Anchor Chain **(Matrix^2 Stretch Resistant Coils only)**	Same as predicate devices
Main Coil / delivery wire junction tubing	Same as predicate devices
Bioabsorbable Polymer	Same as for predicate Matrix SR devices
Adhesive	Same as predicate devices but with formulation change
Delivery Wire	
Core wire w/coating	Same as predicate devices
Proximal Coil	Same as predicate devices
Proximal Marker Coil	Same as predicate devices
Sheath, Delivery Wire (heat shrink tubing)	Same as predicate devices
Proximal Tubing	Same as predicate devices
Bushing	Same as predicate devices
Inner Coil	Same as predicate devices
Packaging	
Dispenser Coil	Same as predicate devices
Introducer Sheath	Same as predicate devices
Flush Port (new component)	Funnel: Pellethane Tube: Polycarbonate Luer Lock: Polycarbonate

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2005

Mr. James Leathley
Regulatory Affairs Project Manager
Boston Scientific Neurovascular
47900 Bayside Parkway
Fremont, California 94538-6615

Re: K050700
Trade/Device Name: Matrix² Detachable Coils [Matrix² Stretch Resistant (SR) Coils, Matrix² 2D Firm Coils, Matrix² 3D Omega Coils, Matrix² 360° Coils, Matrix² 360° Stretch Resistant (SR) Coils]
Regulation Number: 21 CFR 882.5950
Regulation Name: Artificial embolization device
Regulatory Class: II
Product Code: HCG
Dated: March 16, 2005
Received: March 18, 2005

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 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), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050700

Boston Scientific

INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: Matrix^2 Detachable Coils [Matrix^2 Stretch Resistant (SR) Coils, Matrix^2 2D Firm Coils, Matrix^2 3D Omega Coils, Matrix^2 360° Coils, Matrix^2 360° Stretch Resistant (SR) Coils]

Indications for Use:

Matrix^2 Detachable Coils are intended for embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition - are considered by the treating neurosurgical team to be:

a) very high risk for management by traditional operative techniques, or,
b) inoperable,

and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature.

Matrix^2 Detachable Coils are also intended for arterial and venous embolizations in the peripheral vasculature.

Prescription Use √ (Per 21 CFR 801 Subpart D) OR Over The Counter Use _____ (Per 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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