MAY 1 4 2003

K031168

a. 510(k) Summary

Contact Person

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

Trade Name

Matrix™ Stretch Resistant Detachable Coils

Common Name

Occlusion Coil

Classification Name

Artificial Embolization Device (21 CFR Section 882.5950)

Predicate Devices

Number	Description	Predicate for	Clearance Date
K012985 (Boston Scientific)	Matrix Detachable Coil	Matrix Stretch Resistant Detachable Coils	31 January 2003
K030475 (Boston Scientific)	GDC Stretch Resistant Detachable Coils	Stretch Resistant feature of the Matrix Stretch Resistant Coils	14 March 2003

Intended Use

Matrix Detachable Coils are intended for embolization of those 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. Matrix Detachable Coils are also intended for embolization of other neuro vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The Matrix Detachable Coils are also intended for arterial and venous ambolizations in the peripheral vasculature.

Device Description

Matrix Stretch Resistant Detachable Coils are comprised of a platinum-tungsten alloy coil which is coated with a biocompatible absorbable polymer.

Packaging of the device is identical to that of the predicate Matrix Detachable Coils: the finished device is loaded into an introducer sheath and is then placed in a dispenser coil contained within a foil pouch. The foil pouch is then placed into a cardboard display box with a copy of the instructions for use.

Matrix Stretch Resistant Detachable Coils are detached using Boston Scientific's GDC® Power Supply. The system consists of the power supply, powered by two 9 volt batteries, an occlusion coil attached to a delivery wire, a set of connecting cables and a patient return electrode. A positive cable (red) supplies current to the delivery wire while a negative cable (black) completes the circuit by connecting to the patient return electrode (either an adhesive patch attached to the patient's skin or a hypodermic needle inserted subcutaneously through the patient's skin). After placement of the coil in the anatomy, detachment occurs through the electrolytic dissolving of a small portion of the delivery wire.

Principles of Operation

Detachment of the occlusion coil from the delivery wire is accomplished by means of an electrolytic reaction in which the anode, or positive, electrode is the GDC stainless-steel delivery wire, and the cathode, or negative, electrode is a patient return electrode. The body's electrolytes serve as the electrolytic carrier between the two electrodes. Since body fluids are relatively ionic, these fluids serve as good conductors for the minimal electric current generated by the GDC power supply. The GDC is designed so that electrolytic dissolution occurs only in the detachment zone.

Once the power supply circuitry detects coil detachment, the unit will emit 5 audible beeps signaling detachment. In addition, current flow will be stopped and all displays will freeze, indicating values at the time of detachment. This is the "pause" mode, designed to allow the clinician, utilizing fluoroscopy, to confirm that the coil has detached.

If the system has incorrectly signaled coil detachment, the current flow can be re-started by pressing the "Current" switch on the power supply. Restarting the current does not reset the elapsed time display on the power supply.

GDC® Power Supply Description

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

Each time the GDC 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 0.5 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 GDC 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 GDC 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 GDC System and to recognize those changes which indicate detachment.

Once those patterns are identified, the GDC Power Supply signals detachment and stops the flow of current through the GDC System.

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

Coil Dimensional Attributes (compared to the predicate device)

	Matrix™ Stretch Resistant Detachable Coil
Coil Primary Wind OD	Within the range used for the predicate devices.
Secondary Coil OD	Within the range used for the predicate devices.
Coil Wire OD	Within the range used for the predicate devices.
Delivery Wire Length	Same as predicate device.
Delivery Wire Proximal OD	Same as predicate device.
Delivery Wire Distal OD	Within the range used for the predicate devices.

Technological Characteristics Comparison (cont.)

Materials

	Matrix™ Stretch Resistant Detachable Coils
Main Coil	Same as predicate device
Polymer coating	Same as predicate device
Stretch Resistant Thread and anchor chain	Same as predicate device for all except Matrix Standard-SR 2D. Anchor Chain for Matrix Standard-SR 2D utilizes new wire size (0.00125").
Main Coil / delivery wire junction tubing	Same as predicate device
Adhesive	Same as predicate device
Delivery Wire	
Core wire w/coating	Same as predicate device
Proximal Coil	Same as predicate device
Proximal Marker Coil	Same as predicate device
Sheath, Delivery Wire (heat shrink tubing)	Same as predicate device
Proximal Tubing	Same as predicate device
Bushing	Same as predicate device
Inner Coil	Same as predicate device

Verification Test Summary Table:
Matrix Stretch Resistant Devices vs Predicate Matrix™ Devices

Test or Point of Comparison	Matrix™ Stretch Resistant Detachable Coil
Friction	Meets acceptance criteria.
Deployment / Retraction	Meets acceptance criteria.
Catheter Coil Compatibility	Meets acceptance criteria.
Coil Bond Integrity	Meets acceptance criteria.
Suture-to-Coil Bond Integrity	Meets acceptance criteria.
Main Coil Conductivity	Meets acceptance criteria.
Tensile Strength: main coil-to-pusher wire	Meets acceptance criteria.
Tensile Strength: stretch resistant suture	Meets acceptance criteria.
Tensile Strength: distal tip ball	Meets acceptance criteria.
Proximal Coil Stiffness	Meets acceptance criteria.
Acute Particulate	Meets acceptance criteria.
Dynamic Particulate	Meets acceptance criteria.
Suture Degradation	Meets acceptance criteria.

Verification Test Summary Table (cont.):
Matrix Stretch Resistant Devices vs Predicate Matrix™ Devices

Coil Stiffness	Meets acceptance criteria.
Secondary Coil OD Shape Retention	Meets acceptance criteria.
Detachment Time	Modification has no affect upon detachment time
Inner Coil Weld Strength	Modification has no affect upon inner coil weld strength
Coil Migration	Modification has no affect upon coil migration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2003

Mr. Jim Leathley
Regulatory Affairs Project Manager
Boston Scientific Target
47900 Bayside Parkway
Fremont, California 94538

Re: K031168
Trade/Device Name: Matrix™ Stretch Resistant Detachable Coils
Regulation Number: 21 CFR 882.5950
Regulation Name: Artificial embolization device
Regulatory Class: III
Product Code: HCG
Dated: April 11, 2003
Received: April 14, 2003

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 (301) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031168

INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: Matrix Stretch Resistant Coils, comprising:

Matrix™ Standard-SR 2D
Matrix Soft-SR
Matrix Soft-SR 2D
Matrix UltraSoft-SR

Indications for Use:

Matrix Detachable Coils are intended for embolization of those 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. Matrix Detachable Coils are also intended for embolization of other neuro vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The Matrix Detachable Coils are also intended for arterial and venous embolizations in the 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)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031168