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OCT 1 9 2004

Special 510(k): Boston Scientific Neurovascular's GDC® 360° Coils

a. Summary Of Safety And Effectiveness

Contact Person

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

Trade Name

Guglielmi Detachable Coil (GDC®), Class III

Common Name

Occlusion Coil

Classification Name

Artificial Embolization Device (21 CFR Section 882.5950)

Predicate Devices

Number	Description	Predicate for	Clearance Date
K991139 (Boston Scientific / Target)	Guglielmi Detachable Coil (GDC) System with Version 4 Modifications	coil design of: GDC-10 360° Coil **SR** GDC-10 360° Soft Coil **SR** GDC-18 360° Coil	22 Dec. 1999
K001083 (Boston Scientific / Target)	Guglielmi Detachable Coil, Additional GDC Version 4 Modifications	coil design of: GDC-10 360° Coil **SR** GDC-10 360° Soft Coil **SR** GDC-18 360° Coil	3 May 2000
K030475 (Boston Scientific / Target)	Guglielmi Detachable Coil, Modification of a single component of the GDC Stretch Resistant Coil (Anchor 'Twister' to Anchor 'Chain')	Anchor Chain component used on: GDC-10 360° Coil **SR** GDC-10 360° Soft Coil **SR**	14 March 2003

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Intended Use

GDC Power Supply

Boston Scientific Neurovascular's Guglielmi Detachable Coil (GDC) Power Supply is intended for use with all versions of Boston Scientific Neurovascular's Guglielmi Detachable Coils in the embolization of intracranial aneurysms and other vascular malformations of the neuro and peripheral vasculature.

Guglielmi Detachable Coil

The Guglielmi Detachable Coil (GDC) is 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.

The GDC is also intended for arterial and venous embolizations in the peripheral vasculature.

Device Description

The GDC system consists of

- GDC power supply
- GDC occlusion coil attached to a delivery wire
- set of GDC connecting cables
- 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.

GDC 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 GDC devices cleared variously under K991139, K001183 and K030475.

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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 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 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

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Technological Characteristics Comparison (to predicate devices)

Coil Dimensional Attributes

	GDC-10 360° Coil SR GDC®-10 360° Soft Coil SR GDC-18 360° Coil
Coil Wire OD	Same sizes as used with predicate devices
Primary Coil OD	Two new primary coil sizes used with GDC-10 360° Coils; both are within the range of sizes used across all current GDC coils
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
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

	GDC-10 360° Coil SR GDC®-10 360° Soft Coil SR GDC-18 360° Coil
Main Coil	Same as predicate devices
Stretch Resistant Thread **(GDC-10 360° and GDC-10 360° Soft Coils only)**	Same as predicate devices
Main Coil / delivery wire junction tubing	Same as predicate devices
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
Anchor Chain **(GDC-10 360° and GDC-10 360° Soft Coils only)**	Same as predicate devices
Inner Coil	Same as predicate devices

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Technological Characteristics Comparison (cont.)

Power Supply

	GDC-10 360° Coil SR GDC®-10 360° Soft Coil SR GDC-18 360° Coil
Power	Same as for predicate devices
Batteries	Same as for predicate devices
Expected Battery Life	Same as for predicate devices
Red Cable	Same as for predicate devices
Black Cable	Same as for predicate devices
Current Settings	Same as for predicate devices
Current	Same as for predicate devices
Voltage	Same as for predicate devices
Operating Temp.	Same as for predicate devices
Storage Temp.	Same as for predicate devices
Relative Humidity	Same as for predicate devices
Unit Size	Same as for predicate devices
Unit Weight	Same as for predicate devices

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Verification Test Summary Table:
Predicate GDC Devices vs GDC-10 and GDC-18 360° Coils

Test or Point of Comparison	GDC-10 360° Coil SR GDC®-10 360° Soft Coil SR GDC-18 360° Coil
Tensile Strength	Meets acceptance criteria.
Friction	Meets acceptance criteria.
Detachment Time	No change made which would affect this test.
Deployment / Retraction Force	Meets acceptance criteria.
Tip Ball Strength	Meets acceptance criteria.
Coil Stiffness	Meets acceptance criteria.
Heating Effect of Electrolysis	No change made which would affect this test.
Heating Effect of MRI	Meets acceptance criteria.
Electrostatic Discharge	No change made which would affect this test.
Electromagnetic Compatibility-Radiated Susceptibility	No change made which would affect this test.
Electromagnetic Compatibility-Radiated Emissions Class B	No change made which would affect this test.
Electromagnetic Compatibility-Magnetic Immunity	No change made which would affect this test.
Operating System Test (Assembly Source Code)	No change made which would affect this test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2004

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

Re: K042539
Trade/Device Name: Guglielmi Detachable Coil (GDC®-10 360° Coil SR; GDC-10 360° Soft Coil SR, and GDC-18 360° Coil)
Regulation Number: 21 CFR 882.5950
Regulation Name: Artifical embolization device
Regulatory Class: III
Product Code: HCG
Dated: September 17, 2004
Received: September 20, 2004

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) 276-0115. 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/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

Boston Scientific

INDICATIONS FOR USE STATEMENT

510(k) Number: K042539

Device Name: Guglielmi Detachable Coil (GDC®-10 360° Coil SR, GDC-10 360° Soft Coil SR and GDC-18 360° Coil)

Indications for Use:

The Guglielmi Detachable Coil (GDC) is 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.

The GDC is also intended for arterial and venous embolizations in the peripheral vasculature.

Prescription Use __√____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (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)

Miriam C. Provost

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

510(k) Number K042539