12/22/99 K991139

Section 2 - 510 (k) Summary of Safety and Effectiveness and Class III Certification and Summary

a. Summary Of Safety And Effectiveness

Contact Person

Jim Leathley
Senior Regulatory Affairs Specialist
Boston Scientific / Target
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
K962503 (Boston Scientific / Target)	Guglielmi Detachable Coil	All GDC devices which are the subject of this premarket notification	20 Sept. 1996
K971395 (Boston Scientific / Target)	Shelf Life, Various Class II and Class III Devices for	For shelf-life validation method and subsequent placement of shelf-life information on device label	14 July 1997
K914786 (Boston Scientific / Target)	Platinum Fibered Occlusion Coils	For Dacron/Polyester fiber of Fibered GDC	April 1992
K930738 (Deknatel, Division of Howmedica, Inc.)	Surgical Sutures	Suture material for Stretch Resistant GDC	26 July 1994

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Intended 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 neuro vasculature.

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

Fibered GDC is intended for the embolization of vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neuro vasculature. *Fibered 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 the same as that employed for the predicate GDC cleared under K962503.

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The GDC Power Supply is a self-contained, battery-operated unit designed to initiate and control detachment of a GDC coil. It has an on/off button, connections for the GDC cables, and the following controls and displays:

- **Current setting switch and display** - Allows for selection of the different current settings. The selected current (mA) is briefly displayed after which the unit displays the current flowing through the system.
- **Voltage diplay and indicator** - Displays the DC output voltage.
- **Time display** - Displays the elapsed time that the current has been flowing through the GDC system.
- **Check indicator** - Flashes on and off at the beginning of a detachment procedure if there is a poor connection to the patient.
- **Detach indicator** - Flashes on and off when the power supply has detected detachment. Detachment is accompanied by five beeps.
- **Battery indicator** - Illuminates when the voltage of the internal 9-volt batteries falls below specification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 1999

Mr. Jim Leathley
Senior Regulatory Affairs Specialist
Boston Scientific/Target
47900 Bayside Parkway
Fremont, California 94538

Re: K991139
Trade Name: Guglielmi Detachable Coil (GDC) Power Supply
Regulatory Class: III
Product Code: HCG and KRD
Dated: September 29, 1999
Received: October 1, 1999

Dear Mr. Leathley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Neil R.P. Ogden for

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Boston Scientific
TARGET

INDICATIONS FOR USE STATEMENT

510(k) Number: K991139

Device Name: GDC (Guglielmi Detachable Coil) Power Supply

Indications for Use:

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

MRO for 520

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991139

Concurrence of CDRH, Office of Device Evaluation (ODE)

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