JAN 21 2000

K993418

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

a. Summary Of Safety And Effectiveness

Contact Person

Roxane Baxter
Regulatory Affairs Manager
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	*Fibered GDC-18 VortX Shape Guglielmi Detachable Coils*	20 Sept. 1996
K914786 (Boston Scientific / Target)	Occlusion Coils	Dacron, polyester fiber material	20 April 1992
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
K901337 and/or K940982 (Cook, Inc.)	Tornado™ Embolization Coils	Graduated Helical Shape	13 Nov. 1990 14 Oct. 1994

K993418

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.

The intended uses of *Fibered GDC* have been narrowed relative to the predicate GDC, but still fall within the 510(k) cleared intended uses.

Fibered GDC is intended for embolization of vascular abnormalities 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 the following components, each of which is sold separately:

- GDC power supply
- GDC occlusion coil attached to a delivery wire
- set of GDC connecting cables
- patient return electrode
- two 9-volt batteries

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 cleared under K962503.

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 display 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.

Technological Characteristics Comparison

Coil Dimensional Attributes

	Predicate GDC	*Fibered GDC*
Coil Primary Wind OD	0.010" - 0.015"	0.012"
Secondary Coil OD	GDC-10: 2 mm - 30 mm GDC-18: 2 mm - 30 mm	GDC-10: N/A GDC-18: Secondary Coil Apex OD: 2 mm Secondary Coil Base OD: 3, 4, 5 and 6 mm
Coil Wire OD	Range: 0.001" - 0.005" Current wire sizes used in the production of GDC devices are: GDC-10: 0.00175", 0.002" GDC-18: 0.00225", 0.003", 0.004"	 GDC-10: N/A GDC-18: 0.003"
Delivery Wire Length	50 - 200 cm	175 cm
Delivery Wire Proximal OD	GDC-10: 0.010" GDC-18: 0.010"	GDC-10: N/A GDC-18: 0.014"
Delivery Wire Distal OD	GDC-10: 0.0028" GDC-18: 0.0028"	GDC-10: N/A GDC-18: 0.0028"

Technological Characteristics Comparison (cont.)

Materials

	Fibered GDC
Main Coil	Same as predicate device
Fiber Material	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
Hypotube	Same as predicate device

Technological Characteristics Comparison (cont.)

Power Supply

	GDC Power Supply, ***Fibered GDC***
Power	Same as for predicate device.
Batteries	Same as for predicate device.
Expected Battery Life	Same as for predicate device.
Red Cable	Same as for predicate device.
Black Cable	Same as for predicate device.
Current Settings	Same as for predicate device.
Current	Same as for predicate device.
Voltage	Same as for predicate device.
Operating Temp.	Same as for predicate device.
Storage Temp.	Same as for predicate device.
Relative Humidity	Same as for predicate device.
Unit Size	Same as for predicate device.
Unit Weight	Same as for predicate device.

K993418

Verification Test Summary Table:
Comparison of *Fibered GDC* Devices to the Predicate Devices

Test or Point of Comparison	*Fibered GDC*
Friction	Meets acceptance criteria established for predicate devices.
Tensile Strength, Main Coil Weld	Meets acceptance criteria established for predicate device.
Detachment Time	Meets acceptance criteria established for predicate device.
Detachment in Saline w/ particulate analysis	No change was made which would result in the generation of particulate during detachment.
Heating Effect of Electrolysis	No change made which would influence heating effect.
Heating Effect of MRI	No change made which would increase heating effect of MRI.
Main Coil Stretch Test	Meets acceptance criteria established for predicate device.
Fiber Retention Strength	Meets acceptance criteria established for predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 21 2000

Ms. Roxane K. Baxter, RAC
Manager, Regulatory Affairs
Boston Scientific/Target
47900 Bayside Parkway
Fremont, California 94538

Re: K993418
Trade Name: Fibered GDC-18 VortX Shape Guglielmi Detachable Coil
Regulatory Class: III
Product Code: HCG and KRD
Dated: September 29, 1999
Received: October 1, 1999

Dear Ms. Baxter:

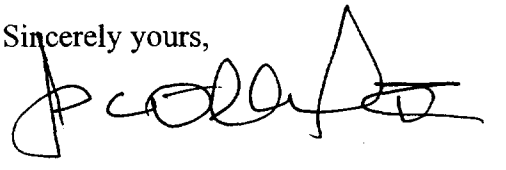
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

This letter will allow you to begin marketing your device as described in your 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 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,



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

Enclosure

K993418

Boston Scientific
TARGET

INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: *Fibered GDC-18 VortX Shape Guglielmi Detachable Coil*

Indications for Use:

The Fibered GDC is intended for embolization of vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature. Fibered GDC is 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 X OR Over The Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993418