P1/2

AUG - 1 2003

July 21, 2003

510(k) Summary

Submitter

Boston Scientific Neurovascular
47900 Bayside Parkway
Fremont, CA 94538-6515

Correspondent

Roxane K. Baxter
Boston Scientific Neurovascular
47900 Bayside Parkway
Fremont, CA 94538- 6515

Contact Information

E-mail: baxterr@bsci.com
Phone: 510-624-2105
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Device Common Name

Occlusion Coil

Device Proprietary Name

Guglielmi Detachable Coil (GDC™)

Device Classification

Class III, HCG; 21 CFR §882.5950

Predicate Device

Trade Name Guglielmi Detachable Coil (GDC™)
Manufacturer Boston Scientific Neurovascular
510(k) Number K001083 (cleared 5/3/2000)

Device Description

The Boston Scientific Neurovascular Guglielmi Detachable Coil (GDC™) is a device which facilitates endovascular embolization of intracranial aneurysms and other vascular abnormalities. The GDC™ Detachable Coil is a platinum/tungsten alloy coil attached to a stainless steel delivery wire. The GDC™ Detachable Coil is detached (using the GDC™ Power Supply) by electrolytically dissolving a small portion of the delivery wire upon its desired placement within an aneurysm or other vascular site via a microcatheter. Multiple coils can be delivered into an aneurysm or other vascular site through the same microcatheter until the aneurysm or other vascular site is densely packed.

Purpose of Submission

Change to Indications For Use
This Premarket Notification has been submitted to obtain clearance for a change in the indications for use of GDC™ Detachable Coils to include all intracranial aneurysms. The proposed change in indications is based on results of the International Subarachnoid Aneurysm Trial (ISAT).

Intended Use

Intended for placement in a blood vessel to permanently obstruct blood flow to an aneurysm or other vascular malformation. (per 21CFR 882.5950)

K031049/2/6

Comparison to Predicate Device

Characteristic	Predicate Device	Proposed Device
Device Name	Guglielmi Detachable Coil (GDC™)	SAME
510 (k)	K001083	CURRENT NOTIFICATION
Device Description (Technological Characteristics)	The Boston Scientific Neurovascular Guglielmi Detachable Coil (GDC™) is a device which facilitates endovascular embolization of intracranial aneurysms and other vascular abnormalities. The GDC™ Detachable Coil is a platinum/tungsten alloy coil attached to a stainless steel delivery wire. The GDC™ Detachable Coil is detached (using the GDC™ Power Supply) by electrolytically dissolving a small portion of the delivery wire upon its desired placement within an aneurysm or other vascular site via a microcatheter. Multiple coils can be delivered into an aneurysm or other vascular site through the same microcatheter until the aneurysm or other vascular site is densely packed.	SAME
Intended Use	Intended for placement in a blood vessel to permanently obstruct blood flow to an aneurysm or other vascular malformation. (per 21CFR 882.5950)	SAME
Indication for Use	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 neurosurgical team to be: a) very high risk for management by traditional operative techniques; or, b) inoperable. GDC™ coils are also intended for embolization of other neuro vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. GDC™ coils are also intended for arterial and venous embolizations in the peripheral vasculature.	Intended for the endovascular embolization of: • Intracranial aneurysms. • Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. • Arterial and venous embolizations in the peripheral vasculature.
Manufacturer	Boston Scientific Neurovascular	Same
Device Classification	Class III, HCG; 21 CFR §882.5950	Same

Summary of Clinical Data

Boston Scientific Neurovascular submitted the 1-year results of the International Subarachnoid Trial (ISAT)[1] that demonstrated a statistically significant reduction in the risk of dependency or death at 1 year post-treatment when patients with ruptured intracranial aneurysms were treated endovascularly with *GDC™ Detachable Coil*s rather than with neurosurgical clipping.

Date Summary Prepared

July 21, 2003

[1] ISAT Collaborative Group. International Subarachnoid Aneurysm Trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2143 patients with ruptured intracranial aneurysms: a randomised trial. *The Lancet* 2002; **360**: 1267-74

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2003

Ms. Roxane K. Baxter
Manager, Regulatory Affairs
Boston Scientific Neurovascular
47900 Bayside Parkway
Fremont, California 94538-6515

Re: K031049
Trade/Device Name: Guglielmi Detachable Coil (GDC™)
Regulation Number: 21 CFR 882.5950
Regulation Name: Artificial Embolization Device
Regulatory Class: III
Product Code: HCG
Dated: March 31, 2003
Received: April 14, 2003

Dear Ms. Baxter:

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

K031049/P1/1

Applicant: Boston Scientific Neurovascular

510(k) Number: K031049

Device Name: Guglielmi Detachable Coil (GDC™)

Indications For Use:

Intended for the endovascular embolization of:

- Intracranial aneurysms.
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.
- Arterial and venous embolizations in the peripheral vasculature.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K031049