PreMarket Notification 510(k) Submission K103355: Boston Scientific's GDC® 360° Detachable Coils – Expanded Indications for Use

FEB 16 2011

510(k) SUMMARY

Submitter

Boston Scientific Corporation
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Correspondent

Rhoda M. Santos
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Contact Information

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Date Summary Prepared 21 January 2011

Device Name / Trade Name

The device trade names and common/classification names are as follows:

Device Trade Name: GDC® 360° Detachable Coil

Common/Classification Name: Occlusion Coil; Vascular Embolization Device; Neurovascular embolization device

Address and Establishment Registration Number

The address and registration numbers for the manufacturer and sterilization sites are:

Manufacturer:

Boston Scientific Cork Ltd.
Business & Technology Park
Model Farm Road
Cork,
Ireland

FDA Registration # 9616684
(Establishment Registration Number)

Sterilization Site:

Isotron Ireland Ltd.
IDA Business and Technology Park
Tullamore,
County Offaly
Ireland

PreMarket Notification 510(k) Submission K103355: Boston Scientific's GDC® 360° Detachable Coils – Expanded Indications for Use

Device Classification Regulation Number and Regulatory Status

GDC® 360° Detachable Coils are vascular and neurovascular embolization devices under 21 CFR 870.3300 (KRD) and 21 CFR 882.5950 (HCG), respectively. The devices are Class II devices (special controls), the special control for which is FDA's guidance document, *Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices* (issued 29 Dec 2004).

Predicate Device Information

Predicate devices are Boston Scientific's Guglielmi Detachable Coils (GDC®) and GDC® 360° Detachable Coils cleared under the following submissions:

- **K031049**, ISAT Indication for all GDC® devices (cleared 1 August 2003);
- **K042539**, Guglielmi Detachable Coil 360° Coils (cleared 19 October 2004).

Device Description

Boston Scientific's GDC® 360° Detachable Coil is a device which facilitates endovascular embolization of intracranial aneurysms and other vascular abnormalities. The GDC® 360° Detachable Coil is a platinum/tungsten alloy coil attached to a stainless steel delivery wire. The GDC® 360° Detachable Coil is detached (using the Boston Scientific Detachable Coil Power Supply or InZone™ Detachment System) 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.

The GDC® 360° coil is first wound into a primary or main coil and then into a secondary shape using a secondary shaping (winding) mandrel. The distal end of the main coil is formed such that there is a smaller distal loop at the end of the main coil, the diameter of which is 75% that of the main coil to facilitate placement of the coil into an aneurysm.

The GDC® 360° Detachable Coil is a line extension to the GDC® family of devices and include the following coil subtypes:

- GDC®-10 360° Coil
- GDC®-10 360° Soft Coil, and
- GDC®-18 360° Coil

The primary differences between the GDC® and the GDC® 360° Coil include the following:

- a slightly modified shape relative to the predicate GDC® coils (accomplished through use of a new secondary coil winding mandrel)
- an expanded range of coil sizes (i.e., in terms of coil outside, or secondary, diameter and coil length) and,

- minor additional changes related to these two changes noted above.

Purpose of Submission

This Premarket Notification has been submitted to obtain clearance for a change in the indications for use of GDC® 360° Detachable Coils to include patients with ruptured intracranial aneurysms for whom surgical intervention is feasible. The proposed change in indications is based on results of the International Subarachnoid Aneurysm Trial (ISAT). There are no other changes to the GDC® 360° device as a result of the expanded indications, compared to the device described in K042539 (cleared 19 October 2004).

Comparison to Predicate Device

Characteristic	Predicate Device	Predicate Device	Proposed Device
Device Name	Guglielmi Detachable Coil (GDC®)	Guglielmi Detachable Coil (GDC® 360°) Detachable Coil	Guglielmi Detachable Coil (GDC® 360°) Detachable Coil
510 (k)	K031049 (cleared 1 August 2003)	K042539 (cleared 19 October 2004)	CURRENT NOTIFICATION
Device Description (Technological Characteristics)	Boston Scientific's 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 Boston Scientific Detachable Coil Power Supply or InZone™ Detachment System) 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.	Boston Scientific's Guglielmi Detachable Coil (GDC® 360°) Detachable Coil is a device which facilitates endovascular embolization of intracranial aneurysms and other vascular abnormalities. The GDC® 360° Detachable Coil is a platinum/tungsten alloy coil attached to a stainless steel delivery wire. The GDC® 360° Detachable Coil detached (using the Boston Scientific Detachable Coil Power Supply or InZone™ Detachment System) 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 as predicate GDC 360° Detachable Coil.
Indications for Use/Intended	Guglielmi Detachable Coils are intended for the endovascular	GDC 360° Detachable Coils are intended for embolization of those	GDC 360° Detachable Coils are intended for the endovascular

Use	embolization of: • Intracranial aneurysms • Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistula • Arterial and venous embolizations in the peripheral vasculature	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 embolization of other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. GDC 360° Coils are also intended for arterial and venous embolizations in the peripheral vasculature.	embolization of: • Intracranial aneurysms • Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistula • Arterial and venous embolizations in the peripheral vasculature
Manufacturer	Boston Scientific Corporation	Same	Same
Device Classification	Class II (Special Controls), HCG, 21 CFR §882.5950 Class II (Special Controls), KRD, 21 CFR §870.3300	Same	Same

Summary of Non-Clinical Data

A summary of the Non-clinical bench testing performed on the GDC® 360° coils is provided in Table 1. These test results were previously provided in **K042539**, cleared 19 October 2004.

Table 1: Verification Test Summary
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 (Main coil to delivery wire)	Meets same acceptance criteria as predicate device (K03149)
Friction (Coil deployment resistance through a microcatheter)	Meets same acceptance criteria as predicate device (K03149)
Detachment Time	No change made which would affect this test.
Deployment / Retraction Force	Meets same acceptance criteria as predicate device (K03149)
Tip Ball Strength	Meets same acceptance criteria as predicate device (K03149)
Coil Stiffness	Meets same acceptance criteria as predicate device (K03149)
Heating Effect of Electrolysis	No change made which would affect this test.
Heating Effect of MRI	Meets same acceptance criteria as predicate device (K03149)
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.

Conclusion

The Non-clinical testing has demonstrated that the GDC® 360° coils are substantially equivalent to the predicate GDC® coils (K03149, cleared 1 August 2003).

PreMarket Notification 510(k) Submission: Boston Scientific's GDC® 360° Detachable Coils – Expanded Indications for Use

Summary of Clinical Data

Boston Scientific Corporation previously submitted the 1-year results of the International Subarachnoid Aneurysm Trial (ISAT)[1] with K031049, which 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 Coils* rather than with neurosurgical clipping. Subsequent long term studies of the ISAT trial have been published in the Lancet Neurology[2] by the investigators. The data showed that the risk of death at five years for patients with a ruptured intracranial aneurysm treated with endovascular coil embolization was significantly lower compared to patients who underwent surgical clipping. Overall, the ISAT follow-up data for a mean of 9 years (range 6-14 years) demonstrate that the risk of rebleeding from a treated aneurysm is low and although there were more rebleeds from the treated aneurysm in the coiling group than in the clipping group, there was no difference between the two groups in the number of deaths due to rebleeding. This improvement in patient outcomes compared to surgical clipping demonstrates that the GDC® 360° Coils with the proposed indications change is as safe and effective as the predicate GDC® 360° Coils with current indications.

Conclusion

Based on the results of the clinical data of the ISAT, which demonstrate improvement in patient outcomes, and the similarities of the design, materials, and processes of the GDC® 360° Detachable Coil to the predicate GDC® Detachable Coil, Boston Scientific requests clearance for the Indications for Use on the GDC® 360° Detachable Coil to be the same as is currently referenced for our GDC® devices. Since the requested change in Indications for Use does not alter the fundamental scientific technology of the underlying predicate device and the risk assessment of the modifications raises no new questions of safety and effectivess, Boston Scientific has determined that the subject device is substantially equivalent to the predicate devices cleared under K031049 and K042539.

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[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

[2] Molyneux, A. J., et al., Risk of recurrent subarachnoid haemorrhage, death, or dependence and standardized mortality ratios after clipping or coiling of an intracranial aneurysm in the International Subarachnoid Aneurysm Trial (ISAT): long term follow-up. *Lancet Neurol*, 2009. 8(5): p. 427-33.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Boston Scientific Neurovascular
c/o Ms. Rhoda M. Santos
Senior Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, CA 94538

FEB 16 2011

Re: K103355
Trade/Device Name: GDC® 360° Detachable Coils
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: December 8, 2010
Received: December 9, 2010

Dear Ms. Santos:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K103355

Device Name: GDC® 360° Detachable Coils

Indications for Use:

GDC® 360° Detachable Coils are 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

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JEFFREY TOY

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K103355