MAR - 3 2011

K102912

Section 2 — 510(k) Summary

(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Person	Debbie McIntire Senior Regulatory Affairs Specialist Boston Scientific Debbie.McIntire@bsci.com Phone: (408) 935-4679 Fax: (763) 494-2222
Classification Name	Vascular embolization device
Product Code	KRD
Common or Usual Name	Fibered IDC
Proprietary Name	Interlock™ Fibered IDC™ Occlusion System
Name of Predicate Device	Fibered Interlocking Detachable Coil (Fibered IDC Occlusion System) (K060078)

Device Description	The Interlock Fibered IDC Occlusion System includes a coil (manufactured from platinum-tungsten alloy) that is mechanically attached to a coil delivery wire. This assembly is contained within an introducer sheath. The platinum coil contains synthetic fibers for greater thrombogenicity. The Interlock Fibered IDC Occlusion Coil is designed to be delivered under fluoroscopy with a 0.0 21 in (0.53 mm) inner diameter (I.D.) microcatheter (e.g. Renegade™ Microcatheter) with one or two radiopaque (RO) tip markers. The interlocking delivery wire design allows the coil to be advanced and retracted before final placement in the vessel, thus aiding in more controlled delivery including the ability to withdraw the coil prior to deployment.
Intended Use	The Interlock Fibered IDC Occlusion System is a modified interlocking detachable coil indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. This device is not intended for neurovascular use.
Non-Clinical and Clinical Test Summary	Non-clinical testing demonstrates that the Interlock Fibered IDC Occlusion System will not present additional risk to a patient during a MRI procedure in comparison to risks imposed by gravitational, and other normal daily activities, or a temperature rise that is experienced during a feverish condition. The results of testing conducted under methods described by ASTM F2182-02a, ASTM F2052-06e1, ASTM F2213-06 and ASTM F2119-07 have demonstrated that the Coils are MR Conditional and can be scanned safely under a static magnetic field of 1.5 Tesla or 3.0 Tesla. Testing at field strengths other than 1.5 Tesla or 3 Tesla has not been performed to evaluate coil migration or heating.

Date Prepared: September 2010

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 Corporation
c/o Ms. Shannon Pettit
Senior Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

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Re: K102912
Trade/Device Name: Interlock™ Fibered IDC™ Occlusion System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: February 18, 2011
Received: February 22, 2011

Dear Ms. Pettit:

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 1 — Indications for Use Statement

510(k) Number (if known): K102912

Device Name: Interlock™ Fibered IDC™ Occlusion System

Indications for Use:

The Interlock™ Fibered IDC™ Occlusion System is a modified interlocking detachable coil indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. This device is not intended for neurovascular use.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices