K113651

510(k) Summary

per 21 CFR §807.92 (c)

JAN 11 2012

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Harlan Jones Regulatory Affairs Specialist II Tel: 763-255-0027 Fax: 763-494-2222 E-mail: Harlan.Jones@bsci.com
Date Prepared	December 08, 2011
Trade Name	Interlock™-35 Fibered IDC™ Occlusion System
Common Name	Vascular embolization device
Classification	Class II
Product Code	KRD, Vascular embolization devices (21 CFR 870.3300)
Predicate Device	Interlock-35 Fibered IDC Occlusion System (Vascular embolization device) K112103 SE: 12 Aug 2011
Reason for Submission	The reason for this premarket notification is to seek clearance for a revision to the Directions for Use (DFU) for Boston Scientific Corporation's (BSC) Interlock™-35 Fibered IDC™ Occlusion System (Vascular embolization device). The device was previously cleared by FDA under K112103 as Interlock™-35 Fibered IDC™ Occlusion System (Vascular embolization device).

Device Description	The Interlock-35 Fibered IDC Occlusion System includes a coil manufactured from a 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-35 Fibered IDC Occlusion System is designed to be delivered under fluoroscopy through a 5F (1.70 mm) (0.035 in [0.89 mm] or 0.038 in [0.97 mm] inner lumen) Imager™ II Selective Diagnostic. 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/Indications for Use	The Interlock-35 Fibered IDC Occlusion System is indicated for obstructing or reducing blood flow in the peripheral vasculature during embolization procedures. This device is not intended for neurovascular use.
Non-Clinical Performance Data	Non-clinical performance data was not required since there were no changes made to the device. The modifications made to the DFU do not change the intended use of the device, but were made for clarity.
Conclusion	Modification of the Intended Use/Indications for Use statement in the Interlock-35 DFU was made for clarity. No contraindications have been added or deleted. Instructions for use have been clarified and reworded. Minor modifications to precaution and caution statements were reworded for clarity and consistency. No other changes to labeling have been made. Based on the minor labeling modifications, and no changes to the device, Boston Scientific determined that the Interlock-35 Fibered IDC Occlusion System continues to be appropriate for its intended use.

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 Mr. Harlan Jones
Regulatory Affairs Specialist II
One Scimed Place
Maple Grove, MN 55311

JAN 11 2012

Re: K113651
Trade/Device Name: Interlock™-35 Fibered IDC™ Occlusion System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: December 9, 2011
Received: December 12, 2011

Dear Mr. Jones:

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,

M. A. Hillebran

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

Enclosure

Proposed Intended Use/Indications for Use

510(k) Number (if known): K113651

Device Name: Interlock-35™ Fibered IDC™ Occlusion System

Proposed Intended Use/Indications for Use:

The Interlock-35 Fibered IDC Occlusion System is indicated for obstructing or reducing blood flow in the peripheral vasculature during embolization procedures. This device is not intended for neurovascular use.

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

M J Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113651