510(k) Summary

per 21 CFR §807.92 (c)

MAR - 3 2011

K110295

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311		
Contact Name and Information	Shannon Pettit Senior Regulatory Affairs Specialist Tel: 763-494-2833 Fax: 763-494-2222 E-mail: Shannon.Pettit@bsci.com		
Date Prepared	January 31, 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 Devices	Boston Scientific Interlock Fibered IDC Occlusion System	K060078	SE: 31 Jan 2006
	Fibered Platinum .035" Type Occlusion Coils	K955293	SE: 6 Feb 1996
Reason for Submission	To gain clearance for a modified fibered interlocking detachable coil embolization system based on the currently marketed Fibered IDC Occlusion System cleared under K060078.		

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 (0.035 in [0.89 mm] or 0.038 in [0.97 mm] inner lumen) Diagnostic Catheter (e.g. Imager™ II Diagnostic Catheter). 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.
Indications for Use	The Interlock-35 Fibered IDC Occlusion System is indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. This device is not intended for neurovascular use.
Comparison of Technological Characteristics	The proposed Interlock-35 Fibered IDC Occlusion System is a modification to existing designs/shapes currently marketed by Boston Scientific. It is important to note that each of the Interlock-35 Fibered IDC Occlusion System device characteristics is currently available on BSC legally marketed devices and no changes in fundamental scientific technology have been made. Additionally, the performance characteristics of the Interlock-35 Fibered IDC Occlusion System are substantially equivalent to the currently marketed devices.

Non-Clinical Performance Data	Determination of substantial equivalence is based on an assessment of non-clinical performance data. Non-clinical performance data submitted in support of substantial equivalence is based on the Failure Modes/Effects Analysis (FMEA) risk analysis method completed for the Interlock-35 Fibered IDC Occlusion System to demonstrate that the proposed devices are suitable for their intended use. All testing performed and data demonstrate passing results according to executed verification protocols. Therefore, results of non-clinical performance data submitted supports substantial equivalence to predicate device. The following performance tests were performed: • Coil Geometry • Stretch Resistance • Deployment • Atraumatic Embolic Coil Tip • Fiber Retention • Interlocking Arm to Embolic Coil Tensile Strength • Embolic Coil Corrosion Resistance • Radial Force • Atraumatic Delivery Wire Tip • Interlocking Arm to Delivery Wire Tensile Strength • Corrosion Resistance • Delivery Wire Coating Fracture • Delivery Wire Coating Flexure • Delivery Wire OD • Delivery Wire Length • Introducer Sheath Interface • Introducer Sheath Deliverability • Delivery Catheter Compatibility • Rotating Hemostatic Valve (RHV) Compatibility
Clinical Performance Data	Not applicable; determination of substantial equivalence is not based on an assessment of clinical performance data.

Conclusion	The modifications do not affect the intended use or alter the fundamental scientific technology of the predicate Boston Scientific Interlock Fibered IDC Occlusion System (K060078). Based on the Indications for Use, unaltered technological characteristics, and submitted non-clinical performance data supporting this modification, the Boston Scientific Interlock-35 Fibered IDC Occlusion System is shown to be appropriate for its intended use and demonstrates that the device is as safe, as effective, and performs as well as the predicate device.

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

MAR - 3 2011

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

Re: K110295
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: January 31, 2011
Received: February 1, 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

Indications for Use

510(k) Number (if known): K110295

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

Indications for Use:

The Interlock-35 Fibered IDC Occlusion System is indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. 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)

Susan R. Vachon
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110295