K132578

SEP 13 2013

# 510(k) Summary

**per 21 CFR §807.92**

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| **Submitter's Name and Address** | Boston Scientific Corporation<br>One Scimed Place<br>Maple Grove, MN 55311<br>Phone: 763-494-1700<br>Fax: 763-494-2222 |
| **Contact Name and Information** | Todd Kornmann<br>Principal Regulatory Affairs Specialist<br>Phone: 763-494-1348<br>Fax: 763-494-2222<br>e-mail: todd.kornmann@bsci.com |
| **Date Prepared** | 15 August 2013 |
| **Proprietary Name** | Interlock™ 018 Fibered IDC™ Occlusion System |
| **Common Name** | Vascular embolization device |
| **Product Code** | KRD |
| **Classification** | Class II, 21 CFR Part 870.3300 |
| **Predicate Devices** | Interlock -18 Fibered IDC Occlusion System — K102912, March 3, 2011<br>K060078, January 31, 2006 |
| **Device Description** | The 018 Spiral / Helical 2D Interlock Fibered IDC Occlusion System is a product line consisting of 0.018 inch (0.457 mm) system compatible fibered interlocking detachable coils. 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 0.021 inch (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/ 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. |
| **Comparison of Technological Characteristics** | The proposed line extension of the 018 Spiral / Helical 2D Interlock Fibered IDC Occlusion System incorporates substantially equivalent design, packaging, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate BSC Interlock Fibered IDC Occlusion System. |

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| **Performance Data** | Determination of substantial equivalence for the 018 Spiral / Helical 2D Interlock Fibered IDC Occlusion System bench testing is based on an assessment of non-clinical bench and biocompatibility testing. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing and, therefore, these devices may be considered substantially equivalent to the predicate devices.<br>The following biocompatibility and chemical characterization tests were completed on the 018 Spiral / Helical 2D Interlock Fibered IDC Occlusion System:<br>Cytotoxicity — Hemolysis (Extract Method)<br>Sensitization — Complement Activation<br>Intracutaneous Reactivity — Implantation<br>Acute Systemic Toxicity — Genotoxicity (Ames Assay and Mouse Lymphoma)<br>Materials Mediated Pyrogenicity — Subacute Toxicity (IP and IV)<br>USP Physicochemical — Latex<br>Partial Thromboplastin Time<br>The following in-vitro performance tests were completed on the 018 Spiral / Helical 2D Interlock Fibered IDC Occlusion System:<br>Anchorability — Deliverability/Pushability<br>Fiber Retention — Stretch Resistance<br>Microcatheter Compatibility (lumen) |
| **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 (K102912, cleared March 3, 2011 and K060078, cleared January 31, 2006).<br>Based on the indications for use, technological characteristics, safety and performance testing, the proposed line extension of the 018 Spiral / Helical 2D Interlock Fibered IDC Occlusion System is appropriate for the intended uses and are considered to be substantially equivalent to the predicate Interlock Fibered IDC Occlusion Systems (K102912, cleared March 3, 2011 and K060078, cleared January 31, 2006). |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 13, 2013

Boston Scientific Corporation
C/O Todd Kornmann
One Scimed Place
Maple Grove, MN 55311

Re: K132578
Trade/Device Name: Interlock™ - 18 Fibered ICD™ Occlusion System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: August 15, 2013
Received: August 16, 2013

Dear Mr. Kornmann:

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 contact 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. 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,

Melissa A. Torres -S

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

## Indications for Use

510(k) Number (if known): K132578

Device Name: Interlock™ -18 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.

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| Prescription Use X<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(21 CFR 801 Subpart C) |

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Melissa A. Torres -S