FEB 11 2011

K102714

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	1) 0.018 Fibered Platinum Coils 2) 0.035 Fibered Platinum Coils
Proprietary Name	1) VortX-18™ , VortX™ Diamond -18, Straight-18, Figure 8-18, Multi-Loop-18, Complex Helical-18 Fibered Platinum Coil 2) VortX™-35, 2D Helical-35 Fibered Platinum Coils
Names of Predicate Devices	1) Target Therapeutics Peripheral Coils (K914786) 2) Target Therapeutics Fibered Platinum Coils (K955293)
Reason for Submission	Modifications to the device labeling related to MRI compatibility.

Device Description	1) Boston Scientific's 0.018 Fibered Platinum Coils consist of platinum-tungsten alloy coils with synthetic fibers and are available in six different shapes; Vortx, Vortx Diamond, Complex Helical, Figure-8, Multi-Loop and Straight. The coil is provided with an introducer that is secured at both ends by a retaining clip during shipping and storage. The coil plunger, supplied with the coil, is used to push the coil out of the introducer and into the microcatheter. 2) Boston Scientific VortX-35 and 2D Helical-35 Fibered Platinum Coils are helically-shaped platinum-tungstent alloy coils with synthetic fibers. The coils are provided with an introducer that is secured at both ends by a retaining clip during shipping and storage. A coil plunger, supplied with the coil, is used to push the coil out of the introducer and into the catheter.
Intended Use	Boston Scientific's 0.018 and 0.035 Fibered Platinum Coils are intended for arterial and venous embolizations in the peripheral vasculature.
Non-Clinical and Clinical Test Summary	Non-clinical testing demonstrates that the Vortx-18, Vortx Diamond-18, Straight-18, Figure 8-18, Multi-Loop-18, Complex Helical-18, Vortx-35 and 2D Helical-35 Fibered Platinum Coils 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 F2182-09, 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 in normal operating mode,and in a static magnetic field gradient less than 25 T/m. 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 Corp.
c/o Ms. Shannon Pettit
Senior Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

FEB 11 2011

Re: K102714
VortX™-18, VortX™ Diamond-18, Straight-18, Figure 8-18, Multi-Loop-18, and Complex Helical-18 Febered Platinum Coils
VortX™-35 and 2D Helical-35 Fibered Platinum Coils
Regulation Number: 21 CFR 870.3300
Regulation Name: Device, Embolization, Vascular
Regulatory Class: Class II (two)
Product Code: KRD
Dated: January 6, 2011
Received: January 7, 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): K102714

Device Name: VortX-18™ , VortX™ Diamond -18, Straight-18, Figure 8-18, Multi-Loop-18, Complex Helical-18 Fibered Platinum Coil and VortX™-35, 2D Helical-35 Fibered Platinum Coils

Indications For Use:

Boston Scientific's 0.018 and 0.035 Fibered Platinum Coils are intended for arterial and venous embolizations in the peripheral vasculature.

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)

Donna R. Vickman
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102714