



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Boston Scientific  
% Mr. George Prendergast  
Senior Regulatory Affairs Specialist  
47215 Lakeview Blvd.  
FREMONT CA 94538

September 22, 2015

Re: K152403  
Trade/Device Name: Permanent Sled Bag  
Regulation Number: 21 CFR 892.1570  
Regulation Name: Diagnostic ultrasonic transducer  
Regulatory Class: II  
Product Code: ITX  
Dated: August 21, 2015  
Received: August 25, 2015

Dear Mr. Prendergast:

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 Industry and Consumer Education 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” (21 CFR 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 Industry and Consumer Education 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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a large, prominent "R" and "O".

Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

**K152403**

Device Name

Permanent Sled Bag

Indications for Use (Describe)

The sterile bag is intended to cover the motordrive/sled assembly during intravascular ultrasound procedures to maintain the sterile field and prevent transfer of microorganisms, body fluids and particulate material to the patient and healthcare worker.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) Summary**  
**Boston Scientific Corporation**  
**Permanent Sled Bag**

This 510(k) Summary is provided in this Premarket Notification in accordance with requirements of the Safe Medical Device Act (SMDA) of 1990. The content is submitted in conformance with 21 CFR Part 807.92.

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**Submitted By:** Boston Scientific Corporation  
47215 Lakeview Blvd.  
Fremont, CA. 94538

**Contact Person:** George J. Prendergast  
Senior Regulatory Affairs Specialist  
Tel: 510-624-1634  
Fax: 510-440-7698  
George.Prendergast@bsci.com

**Date: Prepared:** August 21, 2015

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**Proprietary Name:** Permanent Sled Bag

**Common Name:** Sterile Cover

**Classification Name:** Class II  
Transducer, Ultrasonic, Diagnostic (accessory)  
21 CFR Part 892.1570 (90ITX)  
Radiology/Cardiology Panel

**Product Code:** 90ITX

**Predicate Device:**

Product	510(k)	Clearance Date
MDU5 PLUS Sterile Bag	K130243	March 1, 2013

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Boston Scientific Corporation  
Special 510(k)  
Permanent Sled Bag

**Description of the Device:**

The Permanent Sled Bag is a sterile, single-use device. It will be used with the iLab Ultrasound Imaging System. It is intended to cover the MDU5 PLUS motordrive/permanent sled assembly during intravascular ultrasound procedures and prevent transfer of microorganisms, body fluids and particulate material to the patient and healthcare worker. The device consists of a long, narrow bag made of low density polyethylene and is e-beam sterilized. The bag is folded and packaged in a Tyvek®/Nylon or equivalent medical device packaging suitable for e-beam sterilization. The Permanent Sled Bag will not impede the 10cm travel of the sled. There is a faceplate that is attached to the Permanent Sled Bag that attaches to the MDU5PLUS motordrive. The Permanent Sled Bag is sufficiently clear as to not impede viewing of the MDU5PLUS display. The Permanent Sled Bag must not interfere with the installation of the MDU5PLUS/permanent sled assembly. The Permanent Sled Bag will be available as a standalone product or with IVUS catheters.

Tyvek® is a registered trademark of E.I du Pont de Nemours

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**Intended Use / Indications For Use:**

The sterile bag is intended to cover the motordrive/sled assembly during intravascular ultrasound procedures to maintain the sterile field and prevent transfer of microorganisms, body fluids and particulate material to the patient and healthcare worker.

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**Technological Characteristics:**

The modified Permanent Sled Bag employs the same Indications for Use, fundamental scientific technology, and principle of operation as its predicate device.

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**Determination of Substantial Equivalence: Non-Clinical Data**

Determination of substantial equivalence is based in part on an assessment of non-clinical performance data. Non-clinical data included design verification (Bench/Performance Testing, Sterilization Validation and Microbiological Product Evaluation) of

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the proposed Permanent Sled Bag. All predetermined acceptance criteria were met during design verification as specified in the requirements of 21 CFR 820.30. The design verification testing results did not raise different questions of safety and effectiveness associated with changes made to the device.

*Bench/Performance Testing*

Design verification bench/performance testing included the following tests which passed based on a Pass/Fail basis: End Seal Strength, Tabs/Stickers, Grip Points, Functional Efficiency, Display Viewing, MDU5PLUS Movement, Unit Compatibility, System Preparation with Sled, RoHS Compliance.

*Non-Clinical Testing Conclusion*

The non-clinical testing demonstrates the proposed device is as safe and as effective and performs as well as or better than the legally marketed device.

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**Clinical Data / Animal Data:**

No clinical or animal data were generated to support this submission.

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**Conclusion:**

The proposed modifications to the Permanent Sled Bag described in this submission are substantially equivalent to the predicate device. The proposed modifications and labeling are not substantial changes. They do not significantly affect the safety and efficacy of the device.