



May 31, 2016

Boston Scientific Limited  
Ms. Lisa Mee  
Senior Regulatory Affairs Specialist  
One Scimed Place  
Maple Grove, MN 55311

Re: K151253

Trade/Device Name: 2cm Peripheral Cutting Balloon Microsurgical Dilatation Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: PNO  
Dated: May 8, 2015  
Received: May 12, 2015

Dear Ms. Mee,

This letter corrects our substantially equivalent letter of June 10, 2015.

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 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,

**Misti L. Malone -S**

for 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)  
K151253

Device Name  
2cm Peripheral Cutting Balloon® Microsurgical Dilatation Catheter

Indications for Use (Describe)

The Peripheral Cutting Balloon catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

**510k Summary**  
**Per 21 CFR §807.92**

<b>Submitter's Name and Address</b>	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311		
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<b>Date Prepared</b>	8 May 2015		
<b>Proprietary Name</b>	2cm Peripheral Cutting Balloon® Microsurgical Dilatation Catheter		
<b>Common Name</b>	Percutaneous Transluminal Angioplasty Dilatation Catheter		
<b>Product Code</b>	LIT – Catheter, Angioplasty, Peripheral, Transluminal		
<b>Classification</b>	Class II, 21 CFR Part 870.1250		
<b>Predicate Device(s)</b>	2cm Peripheral Cutting Balloon® Microsurgical Dilatation Catheter	K041993	Aug 16, 2004
	2cm Peripheral Cutting Balloon® Microsurgical Dilatation Catheter	K070951	June 04, 2007
<b>Device Description</b>	<p>The 2cm PCB is an Over-The-Wire (OTW) catheter packaged as sterile and intended for single use in a radiology suite/catheterization laboratory/operating room in conjunction with radiologic equipment for fluoroscopic imaging. The device consists of a double-lumen catheter with a non-compliant balloon attached at the distal tip. One of the lumens connects the Y-Adaptor to the proximal end of the outer shaft and the other connects the Y-Adaptor wire port extending from the wire lumen to the distal end of the balloon. The outer lumen is the balloon inflation lumen and is used to inflate and deflate the balloon during the procedure. The inner lumen is used to pass the catheter over a guidewire. The product is intended to pass a 0.018" (0.46 mm) guidewire. The catheter useable length (effective length) is measured from the distal end of the strain relief to the tip and is available in three sizes – 50 cm, 90 cm and 135 cm. Radiopaque markers are placed on the guidewire tubing at the ends of the atherotomes to provide visual reference points for balloon positioning within the vessel. The device is coated with MDX 4-4159 silicone coating.</p>		
<b>Intended Use of Device</b>	The Peripheral Cutting Balloon catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) of obstructive lesions of synthetic or native arteriovenous dialysis fistulae.		

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<b>Comparison of Technological Characteristics</b>	The 2cm PCB incorporates substantially equivalent device materials, design, packaging, catheter configuration, fundamental technology, manufacturing processes, sterilization process, and intended use/indication for use as those in the Boston Scientific predicate devices, K041993 and K070951.														
<b>Performance Data</b>	<p>Bench testing was performed to support a determination of substantial equivalence. 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. The following in-vitro performance tests were completed:</p> <table border="0" data-bbox="521 719 1253 953"> <tr> <td>Balloon Compliance</td> <td>Freedom from Leakage</td> </tr> <tr> <td>Balloon Rated Burst Pressure</td> <td>Blade Attach</td> </tr> <tr> <td>Balloon Multiple Inflation</td> <td>Guide Catheter Compatibility</td> </tr> <tr> <td>Balloon Deflation Time</td> <td>Particulate Release</td> </tr> <tr> <td>Introducer Sheath Compatibility</td> <td></td> </tr> <tr> <td>Bond Strength</td> <td></td> </tr> <tr> <td>Crossing Profile</td> <td></td> </tr> </table>	Balloon Compliance	Freedom from Leakage	Balloon Rated Burst Pressure	Blade Attach	Balloon Multiple Inflation	Guide Catheter Compatibility	Balloon Deflation Time	Particulate Release	Introducer Sheath Compatibility		Bond Strength		Crossing Profile	
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<b>Conclusion</b>	<p>The following biocompatibility tests were completed:</p> <table border="0" data-bbox="521 1044 1292 1304"> <tr> <td>In Vitro Cytotoxicity</td> <td>Direct Contact Hemolysis</td> </tr> <tr> <td>Guinea Pig Maximization Sensitization</td> <td>Complement Activation C3a and SC5b-9 Assay</td> </tr> <tr> <td>Intracutaneous Reactivity</td> <td>Indirect Extract Hemolysis</td> </tr> <tr> <td>Acute Systemic Injection</td> <td>Partial Thromboplastin Time</td> </tr> <tr> <td>Materials Mediated Rabbit Pyrogen</td> <td>In Vitro Hemocompatibility</td> </tr> <tr> <td>Ames Mutagenicity</td> <td>USP Physicochemical</td> </tr> <tr> <td>Mouse Lymphoma Assay</td> <td>Natural Rubber Latex</td> </tr> </table> <p>Based on the indications for use, technological characteristics, and safety and performance testing, the proposed 2cm PCB Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Boston Scientific predicate 2cm PCB Dilatation Catheter.</p>	In Vitro Cytotoxicity	Direct Contact Hemolysis	Guinea Pig Maximization Sensitization	Complement Activation C3a and SC5b-9 Assay	Intracutaneous Reactivity	Indirect Extract Hemolysis	Acute Systemic Injection	Partial Thromboplastin Time	Materials Mediated Rabbit Pyrogen	In Vitro Hemocompatibility	Ames Mutagenicity	USP Physicochemical	Mouse Lymphoma Assay	Natural Rubber Latex
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