



Food and Drug Administration  
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May 19, 2016

Boston Scientific Corporation  
Ms. Carah Kucharski  
Regulatory Affairs Specialist  
One Scimed Place  
Maple Grove, Minnesota 55311-1566

Re: K152842

Trade/Device Name: WALLSTENT™ RP Endoprosthesis Tracheobronchial,  
WALLSTENT™ Endoprosthesis Tracheobronchial

Regulation Number: 21 CFR 878.3720

Regulation Name: Tracheal Prosthesis

Regulatory Class: Class II

Product Code: JCT

Dated: April 18, 2016

Received: April 19, 2016

Dear Ms. Kucharski:

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,

*Tejashri Purohit-Sheth, M.D.*

**Tejashri Purohit-Sheth, M.D.**  
Clinical Deputy Director  
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.  
Director  
Division of Anesthesiology,  
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Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K152842

Device Name

WALLSTENT™ RP Endoprosthesis Tracheobronchial/ WALLSTENT™ Endoprosthesis Tracheobronchial

Indications for Use (Describe)

The WALLSTENT RP Endoprosthesis and WALLSTENT Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

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

May 18<sup>th</sup>, 2016

<b>Common or Usual Name</b>	Self-Expanding Stent
<b>Trade Name(s)</b>	WALLSTENT™ RP Endoprosthesis Tracheobronchial and WALLSTENT™ Endoprosthesis Tracheobronchial
<b>Product Code</b>	JCT – Prosthesis, Tracheal, Expandable
<b>Classification of Device</b>	The WALLSTENT Endoprosthesis Tracheobronchial device has been classified as Class II devices according to 21 CFR 878.3610 – Esophageal Prosthesis.
<b>Submitter's Name and Address</b>	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311-1566
<b>Contact Name and Information</b>	Carah Kucharski Regulatory Affairs Specialist Phone: 763-494-1683 Fax: 763-255-0738 Email: carah.kucharski@bsci.com
<b>Section 514 of the Act Performance Standards</b>	Currently no FDA mandated or voluntary performance standards exist for this device.
<b>Establishment Registration Numbers</b>	<b>Owner /Operator:</b> Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 ERN: 3005099803  <b>Manufacturing Facility:</b> Boston Scientific Ireland Ltd. (BSIL) Ballybrit Business Park Galway, Ireland ERN: 9681260
<b>Predicate Devices</b>	WALLSTENT™ Tracheobronchial Endoprosthesis K992510 cleared November 18, 1999.

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**Intended Use/  
Indications for Use**

The WALLSTENT™ RP Endoprosthesis and WALLSTENT™ Endoprosthesis Tracheobronchial are indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

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**Description of  
Device**

The WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial are comprised of two components: The implantable metallic stent and the UNISTEP Plus delivery system. The stent is composed of biomedical superalloy wire, braided in a tubular mesh configuration. This design configuration results in a stent that is flexible, compliant, and self-expanding. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during delivery. Radiopaque marker bands situated on the interior and exterior tubes aid in imaging during deployment. Small stent sizes (5mm-12mm) may have a radiopaque core to improve radiopacity. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035 in (0.89mm) guidewire.

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**Comparison of  
Required  
Technological  
Characteristics**

The proposed WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial is substantially equivalent to the existing Wallstent Endoprosthesis Tracheobronchial cleared by FDA under premarket notification K992510 (November 18, 1999). WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial has the same intended use, scientific technology, design, sterilization method, and packaging as the applicable predicate device. The only difference is to the MR Safety labeling information within the Directions for Use.

Bench testing in accordance with current FDA guidance supports a labeling as MR Conditional.

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**Summary of Non-  
Clinical Test  
Summary**

Bench testing was performed in accordance with FDA guidance document *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment*, dated December 11, 2014) to support labeling as MR Conditional. 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 device testing.

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**Conclusion**

Based on the indications for use, technological characteristics, and safety and performance testing, the proposed WALLSTENT RP Endoprosthesis Tracheobronchial and WALLSTENT Endoprosthesis Tracheobronchial has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the WALLSTENT Endoprosthesis Tracheobronchial (K992510).

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