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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Boston Scientific Corporation  
% Ms. Angela Byland  
Manager, Regulatory Affairs  
Cardiovascular  
Two Scimed Place  
Maple Grove, Minnesota 55311-1566

Re: K980163

Trade/Device Name: WALLSTENT® Tracheobronchial Prosthesis and Wallstent  
Tracheobronchial Endoprosthesis with Permalume covering

Regulation Number: 21 CFR 878.3720

Regulation Name: Tracheal prosthesis

Regulatory Class: II

Product Code: JCT

Dated: January 15, 1998

Received: January 16, 1998

Dear Ms. Byland:

This letter corrects our substantially equivalent letter of March 13, 1998.

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 (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.

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); good manufacturing practice requirements as set

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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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

## Indications for Use

510(k) Number (if known): K980163

Device Name: Wallstent® Tracheobronchial Prosthesis and Wallstent  
Tracheobronchial Endoprosthesis with Permalume covering

Indications for Use:

The Wallstent Tracheobronchial Endoprosthesis is intended for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

The Wallstent Tracheobronchial Endoprosthesis with Permalume® Covering is intended for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

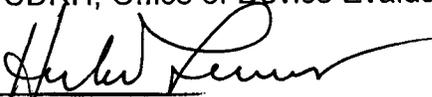
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(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)

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

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## 510(K) SUMMARY K980163

### 1. Submitter:

Boston Scientific Corporation  
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Marlborough, MA 01545  
Telephone: 508-683-4942  
Fax: 508-683-5939

Contact: Kathleen Morahan  
Director Regulatory Affairs  
Original Date Prepared: January 12, 1998  
Revision Date: July 14, 2006

### 2. Device:

Trade Name: Wallstent® Tracheobronchial Endoprosthesis with Unistep Plus Delivery System  
Common Name: Tracheal Prosthesis  
Classification Name: Tracheal Prosthesis  
Regulation Number: 878.3720  
Product Code: JCT  
Classification: Class II

Trade Name: Wallstent Tracheobronchial Endoprosthesis with Permalume Covering and Unistep Plus Delivery System  
Common Name: Tracheal Prosthesis  
Classification Name: Tracheal Prosthesis  
Regulation Number: 878.3720  
Product Code: JCT  
Classification: Class II

### 3. Predicate Device:

Boston Scientific Corporation's Wallstent Tracheobronchial Prosthesis with Unistep Delivery System, K934116

Boston Scientific Corporation's Wallstent Tracheobronchial Prosthesis with Unistep Plus Delivery System, K964121

### 4. Device Description:

The Wallstent Tracheobronchial Endoprosthesis is a self-expanding prosthesis constructed of biomedical superalloy and an elastomeric polymer. Smaller diameter models may utilize a radiopaque core. The prosthesis is a braided wire structure which may be covered with an elastomeric polymer in selected models. The outward radial force along with the ends of the

device serve to stabilize the prosthesis after implanted. The prosthesis is offered in covered and uncovered version to allow physicians to select the most appropriate models based on their preference and individual patient condition. The stents purpose is to increase or maintain the inner luminal diameter of the tracheobronchial passage.

The stent is placed by means of a delivery system. The delivery system is a coaxial tubing assembly which constrains the prosthesis until it is release in a controlled manner. The release of the stent is accomplished by retracting the outer sheath. The prosthesis is packaged constrained on the delivery system ready for placement. The system is sterile and intended for single use only.

#### **5. Intended Use:**

The Wallstent Tracheobronchial Endoprosthesis is intended for us in the treatment of tracheobronchial strictures produced by malignant neoplasms.

The Wallstent Tracheobronchial Endoprosthesis with Permalume Covering is indicated for use in the treatment of tracheobronchial strictures or fistulas produced by malignant neoplasms.

#### **6. Technological Characteristics:**

The purpose of this 510(k) us to allow an alternate delivery system. Compared to the Unistep Delivery System (K934116), the Unistep Plus delivery system allows the user to partially deploy and then reconstrain the stent to facilitate placement. This feature is presently available in the Wallstent Tracheobronchial Endoprosthesis with Unistep Plus Delivery System (K964121). Compared to the present Unistep Plus Delivery System (K964121), the modified system has different materials for the outer and inner tubing.

#### **7. Performance Data:**

The alternate delivery system can be found substantially equivalent based on results of *in vitro* and *in vivo* deployment testing which demonstrate that deployment forces and handling characteristics are comparable to the current delivery system.

#### **8. Conclusion:**

Boston Scientific Corporation has demonstrated that the Wallstent Tracheobronchial Endoprosthesis with Unistep Plus Delivery System, Wallstent Tracheobronchial Endoprosthesis with Permalume Covering and Unistep Plus Delivery System with modified delivery system is substantially equivalent based on design, test results, and indications for use to the predicate devices.