



NOV - 3 2006

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: K992510

Trade/Device Name: WALLSTENT® Tracheobronchial Endoprosthesis with Unistep™
Plus Delivery System

Regulation Number: 21 CFR 878.3720

Regulation Name: Tracheal prosthesis

Regulatory Class: III

Product Code: JCT

Dated: October 31, 1999

Received: November 3, 1999

Dear Ms. Byland:

This letter corrects our substantially equivalent letter of November 18, 1999.

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

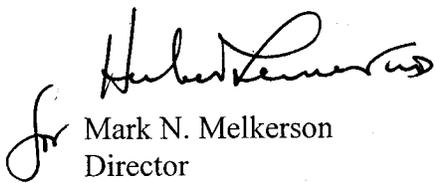
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

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

Indications for Use Statement

510(k) Number
(if known)

K992510

Device Name

WALLSTENT® Tracheobronchial Endoprosthesis with
Unistep™ Plus Delivery System

Indications For Use

The WALLSTENT® Tracheobronchial Endoprosthesis is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

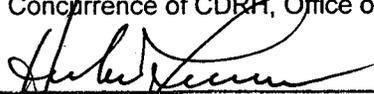
Prescription Use: X
(Per 21 CFR §801 Subpart D)

OR

Over-The-Counter Use: _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K992510

510(k) Summary
K992510

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Angela Byland Manager, Regulatory Affairs Phone: 763-494-2887 Fax: 763-494-2981 e-mail: bylanda@bsci.com
Original Date Prepared	July 26, 1999
Date Prepared	July 14, 2006
Proprietary Name(s)	WALLSTENT® Tracheobronchial Endoprosthesis with Unistep™ Plus Delivery System
Common Name	Tracheal Endoprosthesis
Product Code	JCT
Classification of Device	Class III, 21 CFR Part 878.3720
Predicate Device	WALLSTENT® K964121 December 04, 1996 Tracheobronchial Endoprosthesis
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 stent's purpose is to increase or maintain the inner luminal diameter of the tracheobronchial passage.

**Device
Description
cont'd**

The stent is placed by means of a delivery system. The delivery system is a coaxial tubing assembly that constrains the prosthesis until it is released 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.

**Indications for
Use**

The WALLSTENT® Tracheobronchial Endoprosthesis is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

**Technological
Characteristics**

The purpose of this 510(k) is to allow an alternate delivery system. Compared to the present Unistep™ Plus Delivery System (K964121), this version of the Unistep™ Plus Delivery System has a reduced profile that is a smaller diameter.

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

Conclusion

In summary, Boston Scientific Corporation has demonstrated that the WALLSTENT® Tracheobronchial Endoprosthesis with Unistep™ Plus Delivery System with reduced profile for the delivery system is substantially equivalent based on design, test results, and indications for use to the predicate devices.
