



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: K003100

Trade/Device Name: Wallgraft<sup>®</sup> Tracheobronchial Endoprosthesis with Unistep<sup>™</sup>  
Delivery System

Regulation Number: 21 CFR 878.3720

Regulation Name: Tracheal prosthesis

Regulatory Class: II

Product Code: JCT

Dated: September 29, 2000

Received: October 3, 2000

Dear Ms. Byland:

This letter corrects our substantially equivalent letter of December 20, 2000.

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

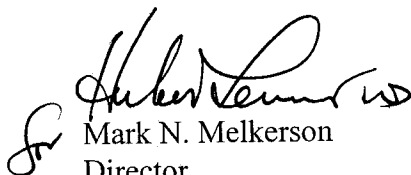
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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)

K003100

Device Name

WALLGRAFT® Tracheobronchial Endoprosthesis with  
Unistep™ Delivery System

Indications For Use

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

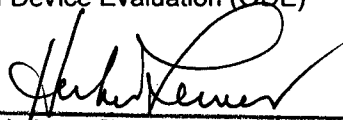
Prescription Use:   X    
(Per 21 CFR §801 Subpart D)

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   K 003100

## 510(k) Summary K003100

<b>Submitter's Name and Address</b>	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311		
<b>Contact Name and Information</b>	Angela Byland Manager, Regulatory Affairs Phone: 763-494-2887 Fax: 763-494-2981 e-mail: bylanda@bsci.com		
<b>Original Date Prepared</b>	September 29, 2000		
<b>Date Prepared</b>	July 14, 2006		
<b>Proprietary Name(s)</b>	WALLGRAFT® Tracheobronchial Endoprosthesis with Unistep™ Delivery System		
<b>Common Name</b>	Tracheal Endoprosthesis		
<b>Product Code</b>	JCT		
<b>Classification of Device</b>	Class II, 21 CFR Part 878.3720		
<b>Predicate Device</b>	WALLSTENT® Tracheobronchial Endoprosthesis	K961296	July 10, 1996
	WALLSTENT® Tracheobronchial Endoprosthesis with Unistep™ Plus Delivery System and WALLSTENT® Tracheobronchial Endoprosthesis with Permalume® Covering and Unistep™ Plus Delivery System	K980163	March 13, 1998
	WALLGRAFT® Tracheobronchial Endoprosthesis with Unistep™ Delivery System	K000001	June 5, 2000

<b>Device Description</b>	<p>The WALLGRAFT® Tracheobronchial Endoprosthesis is a self-expanding prosthesis constructed of biomedical superalloy and a PET covering. The outward radial of the device serves to stabilize the prosthesis after implanted. The stent's purpose is to increase or maintain the inner luminal diameter of the tracheobronchial passage.</p> <p>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.</p>
<b>Intended Use</b>	<p>The WALLGRAFT® Tracheobronchial Endoprosthesis is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.</p>
<b>Technological Characteristics</b>	<p>The purpose of this 510(k) is to allow additional sizes for the WALLGRAFT™ Tracheobronchial Endoprosthesis with Unistep™ Delivery System. Compared to the present WALLSTENT™ Tracheobronchial Endoprosthesis with Unistep™ Delivery System (K964121), this version of the stent has a PET covering and the delivery system has a larger diameter to allow this covering. Compared to the present WALLGRAFT™ Tracheobronchial Endoprosthesis with Unistep™ Delivery System (K000001), this is the same stent and covering in larger diameters and the same delivery system modified for the larger diameters.</p> <p>The alternate stent and delivery system can be found substantially equivalent based on the results of <i>in vitro</i> testing that demonstrates the integrity of the covering and the deployment forces and handling characteristics that are comparable to the current delivery systems.</p>
<b>Conclusion</b>	<p>In summary, Boston Scientific Corporation has demonstrated that the WALLGRAFT™ Tracheobronchial Endoprosthesis with Unistep™ Delivery System is substantially equivalent based on design, test results, and indications for use to the predicate devices.</p>