DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2006

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

Re: K021901
Trade/Device Name: Wallgraft® Tracheobronchial Endoprosthesis with Unistep Plus Delivery System
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal prosthesis
Regulatory Class: II
Product Code: JCT
Dated: June 7, 2002
Received: June 10, 2002

Dear Ms. Byland:

This letter corrects our substantially equivalent letter of July 9, 2002.

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

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,

for 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

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|---|---|
| **510(k) Number (if known)** | K021901 |
| **Device Name** | WALLGRAFT® Tracheobronchial Endoprosthesis with Unistep™ Plus 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** K021901

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# 510(k) Summary
## K021901

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| **Submitter's Name and Address** | Boston Scientific Corporation<br>One Scimed Place<br>Maple Grove, MN 55311 |
| **Contact Name and Information** | Angela Byland<br>Manager, Regulatory Affairs<br>Phone: 763-494-2887<br>Fax: 763-494-2981<br>e-mail: bylanda@bsci.com |
| **Original Date Prepared** | June 7, 2002 |
| **Date Prepared** | July 14, 2006 |
| **Proprietary Name(s)** | WALLGRAFT® Tracheobronchial Endoprosthesis with Unistep™ Plus Delivery System |
| **Common Name** | Tracheal Endoprosthesis |
| **Product Code** | JCT |
| **Classification of Device** | Class II, 21 CFR Part 878.3720 |
| **Predicate Device** | WALLGRAFT® Tracheobronchial Endoprosthesis with Unistep™ Delivery System — K000001 — June 5, 2005 |
| | WALLGRAFT® Tracheobronchial Endoprosthesis with Unistep™ Delivery System — K003100 — December 20, 2000 |

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**Device Description**

The Wallgraft Endoprosthesis with Unistep Plus Delivery System is available in the models indicated in the table below.

A brief description of the stent graft and delivery system components follow.

| Stent Graft Diameter | Stent Graft Length | Delivery System Profile |
|---|---|---|
| 6.0 mm | 20 mm, 30 mm, 50 mm, 70 mm | 9F |
| 7.0 mm | 20 mm, 30 mm, 50 mm, 70 mm | 9F |
| 8.0 mm | 20 mm, 30 mm, 50 mm, 70 mm | 9F |
| 9.0 mm | 20 mm, 30 mm, 50 mm, 70 mm | 10F |
| 10.0 mm | 20 mm, 30 mm, 50 mm, 70 mm | 10F |
| 12.0 mm | 30 mm, 50 mm, 70 mm | 11F |
| 14.0 mm | 50 mm, 70 mm | 12F |

**Stent Graft Description**

The Wallgraft Endoprosthesis (stent graft) consists of a metallic stent comprised of biomedical superalloy monofilament wire with a radiopaque core, braided in a tubular mesh configuration. A platinum nickel micro-cable is incorporated into the stent to enhance radiopacity of the device. A graft material comprised of braided polyester yarn (PET) is adhesively bonded to the outside of the metallic stent. This design configuration results in a stent graft that is flexible, compliant, and self-expanding with the barrier characteristics of a tubular graft.

**Delivery System Description**

The Unistep Plus Delivery System consists of a coaxial tube system. The exterior tube serves to constrain the stent graft over the interior tube until retracted during deployment. The coaxial tubes have the capability of re-constraining the stent graft after partial deployment. A holding sleeve and stent cup, attached to the interior tube, aid in the re-constraining process.

Radiopaque marker bands situated adjacent to the proximal and distal ends of the stent graft facilitate imaging during deployment. A radiopaque marker band located on the exterior tube and a limit marker band on the interior tube function as deployment limit markers. Re-constrainment is possible up to the point where the exterior tube marker band is proximally retracted to the location of the interior tube limit marker.

The interior tube of the coaxial system contains a central lumen which will accommodate a 0.035" guide wire. The delivery system will be available in a single working length of 90 cm.

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| **Intended Use** | The WALLGRAFT® Tracheobronchial Endoprosthesis is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms. |
| **Technological Characteristics** | The modified 9 F - 11 F Unistep Plus Delivery System of the 6 mm to 12 mm Wallgraft Endoprosthesis will be manufactured in a substantially equivalent manner to the currently marketed 12 F delivery system of the 14 mm Wallgraft Tracheobronchial Endoprosthesis with Unistep Plus Delivery System, cleared to market under K003100, December 20, 2000. |
| **Performance Testing** | Testing was conducted to verify that the modified 9 F - 11 F delivery system met product specifications. The following testing was performed:<br>• Total Catheter Length<br>• Catheter Crossing Profile<br>• Deployment Force<br>• Reconstrainment Force<br>• Stent Graft Securement<br>• Hub to Stainless Steel Tube Tensile<br>• Distal Tip Tensile<br>• Inner Member Assembly Tensile<br>• Valve Body to Exterior Tube Tensile<br>• Deployed Stent Graft OD<br>• Post Accelerated Aging Testing<br>• Biocompatibility<br>All test results verified that the modified 9 F - 11 F delivery system is adequate for its intended use. The modified device is considered substantially equivalent to the currently marketed 9 F - 11 F delivery system (K000001) and the 12 F delivery system (K003100). |
| **Conclusion** | In summary, Boston Scientific Corporation has demonstrated that the WALLGRAFT® Tracheobronchial Endoprosthesis with Unistep™ Plus Delivery System is substantially equivalent based on design, test results, and indications for use to the predicate devices. |