



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: K982184

Trade/Device Name: WALLSTENT<sup>®</sup> Tracheobronchial Endoprosthesis  
Regulation Number: 21 CFR 878.3720  
Regulation Name: Tracheal prosthesis  
Regulatory Class: II  
Product Code: JCT, MUM, MQR, FGE, ESW  
Dated: June 18, 1998  
Received: June 22, 1998

Dear Ms. Byland:

This letter corrects our substantially equivalent letter of July 21, 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

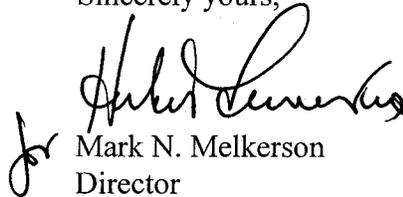
Page 2 – Ms. Angela Byland

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)

K982184

Device Name

WALLSTENT® Tracheobronchial Endoprosthesis

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   K982184

## Indications for Use

510(k) Number (if known): K982184

Device Name: WALLSTENT® Enteral Endoprosthesis

Indications For Use:

The WALLSTENT® Enteral Endoprosthesis is indicated for palliation of duodenal strictures caused by malignant neoplasms.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

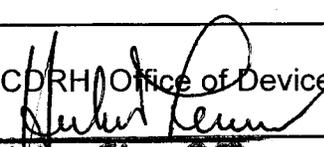
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

---

Concurrence of CD RH Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

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

Page 1 of \_\_\_\_\_

510(k) Number K982184

## Indications for Use

510(k) Number (if known):     K982184    

Device Name:     WALLSTENT® Endoprosthesis    

Indications For Use:

The WALLSTENT® Endoprosthesis is indicated for use in the treatment of biliary 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)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

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

Page 1 of \_\_\_\_\_

510(k) Number     K982184



## Indications for Use

510(k) Number (if known): K982184

Device Name: WALLSTENT® Esophageal Endoprosthesis

Indications For Use:

The WALLSTENT® Esophageal Prosthesis is indicated for palliative treatment of esophageal strictures produced by malignant neoplasms.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

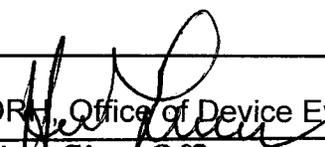
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

---

Concurrence of CDREH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

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

Page 1 of \_\_\_\_\_

510(k) Number K982184

## 510(k) Summary K982184

**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 13, 1998

**Date Prepared**

July 14, 2006

<b>Proprietary Name(s)</b>	WALLSTENT® Tracheo-bronchial Endoprosthesis	WALLSTENT® Enteral Endoprosthesis	WALLSTENT® Biliary Endoprosthesis	WALLSTENT® Esophageal Endoprosthesis
<b>Common Name</b>	Tracheal Endoprosthesis	Esophageal Endoprosthesis	Biliary Stent	Esophageal Endoprosthesis
<b>Product Code</b>	JCT	MUM and MQR	FGE	ESW
<b>Classification of Device</b>	Class III 21 CFR Part 878.3720	Class III 21 CFR Part 878.3610	Class II 21 CFR Part 876.5010	Class III 21 CFR Part 878.3610

**Predicate Device**

1	WALLSTENT® Tracheobronchial Endoprosthesis (12-30 mm)	K980163	March 13, 1998
2	WALLSTENT® Enteral Endoprosthesis (Duodenal)	K980113	April 3, 1998
3	WALLSTENT® Tracheobronchial Endoprosthesis (5-10 mm)	K964121	December 4, 1996
4	WALLSTENT® Biliary (8-10 mm) (Endoscopic and Transhepatic)	K964119	April 28, 1997
5	WALLSTENT® Biliary (12 mm) (Endoscopic and Transhepatic)	K961262	May 16, 1996
6	WALLSTENT® Enteral Endoprosthesis	K954290	July 10, 1996
7	WALLSTENT® Esophageal	K940396	October 2, 1994
8	WALLSTENT® Tracheobronchial Prosthesis	K934116	June 2, 1994

**Device  
Description**

The WALLSTENT® Tracheobronchial Endoprosthesis is a self-expanding prosthesis constructed of braided wire of biomedical superalloy, in some cases partially covered by a polymeric covering. Some models include a radiopaque core. The stent's purpose is to maintain or increase the luminal diameter of the passage in which it is implanted.

The stent is placed by means of a delivery system, which is a coaxial tubing assembly that constrains the prosthesis until it is released in a controlled manner by retraction of the outer tube.

---

**Indications for Use**

1. The WALLSTENT® Tracheobronchial Endoprosthesis is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.
2. Palliative treatment of colonic and duodenal strictures caused by malignant neoplasms.
3. The WALLSTENT® Tracheobronchial Endoprosthesis is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.
4. Treatment of biliary strictures produced by malignant neoplasms.
5. Treatment of biliary strictures produced by malignant neoplasms.
6. Palliative treatment of colonic strictures caused by malignant neoplasms.
7. Treatment of esophageal strictures and tracheoesophageal fistulas produced by malignant neoplasms.
8. The WALLSTENT® Tracheobronchial Endoprosthesis is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

---

**Technological Characteristics**

This premarket notification deals solely with addition of a claim to MRI safety. The design of the product is unchanged.

---

**Conclusion**

The devices are unchanged and there are no changes to safety and efficacy.

The purpose of this 510(k) notification is to present information supporting a labeling change indicating a level of MRI compatibility consistent with current and proposed practices.

---