K073266
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SECTION 5

510(k) Summary

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1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01760-1537

Contact: Neil Kelly
Regulatory Affairs Specialist
Date Prepared: October 30, 2007

2. Device:

Trade Name: WallFlex™ Partially Covered Esophageal Stent System
Common Name: Esophageal Stent
Classification Name: Prosthesis, Esophageal
Product Code: ESW
Classification: Class II per 21 CFR 878.3610

3. Predicate Devices:

Stent:
Ultraflex™ Covered Esophageal NG Stent System (K032930, K012883, K955347, and K940838)
Wallstent™ Esophageal II Stent (K940395)
Polyflex™ Esophageal Stent System (K030559 and K010068)

Delivery System:
Wallflex™ Enteral Colonic Stent System and Anchor Lock Delivery System (K042065)

4. Device Description:

The proposed WallFlex™ Partially Covered Esophageal Stent System consists of a self-expanding metal stent and a delivery system. The proposed stent is manufactured of Nitinol and offered with a partial silicone covering. The stent configurations include two diameters, a 18mm body diameter with a 23mm flare, and a 23mm body diameter with a 28mm flare and three lengths. The 18mm body diameter stent is offered in 103mm, 123mm, and 153mm stent lengths. The 23mm body diameter stent is offered in 105mm, 125mm, and 155mm stent lengths. The proposed delivery system consists of a coaxial tubing assembly that constrains the stent on the delivery catheter shaft until the stent is released.

5. Intended Use:

The proposed device is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistula

6. Technological Characteristics:

The proposed WallFlex™ Partially Covered Esophageal Stent System has similar technological characteristics as the predicate devices. The proposed stent combines the design features of the Ultraflex™ Covered Esophageal NG stent, the Wallstent Esophageal II stent, and the Polyflex Esophageal Stent system. The proposed delivery system has similar technological characteristics to the predicate Wallflex Enteral Colonic Stent System with Anchor Lock Delivery System.

7. Performance Data:

Comparative performance testing was performed to establish substantial equivalence between the proposed WallFlex™ Partially Covered Esophageal Stent System, and the predicate devices. This testing included but was not limited to a dimensional evaluation, radial expansion force, radial compression force, deployment and reconstrainment force, and bond integrity.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed WallFlex™ Partially Covered Esophageal Stent System is substantially equivalent to Boston Scientific Corporation's currently marketed stent systems: Ultraflex™ Covered Esophageal NG Stent, Wallstent Esophageal II Stent System, Polyflex Esophageal Stent System, and the Wallflex Enteral Colonic Stent System with Anchor Lock Delivery System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2008

Mr. Neil Kelly
Regulatory Affairs Specialist
Boston Scientific Corporation
Endoscopy
100 Boston Scientific Way
MARLBOROUGH MA 01752-1234

Re: K073266
Trade/Device Name: WallFlex™ Partially Covered Esophageal Stent System
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: ESW
Dated: February 14, 2008
Received: February 19, 2008

Dear Mr. Kelly:

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 application (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 such 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 begin 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K073266

SECTION 4
Indications for Use Statement

510(k) Number (if known): K073266 ~~To Be Determined~~

Device Name: WallFlex™ Partially Covered Esophageal Stent System

Indications For Use:

The proposed device is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistula

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 Reproductive, Abdominal,
and Radiological Devices
510(k) Number K073266