SECTION 5
510(k) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4454
Fax: 508-683-5939

Contact: Marybeth Gamber
Manager, Regulatory Affairs
Date Prepared: May 21, 2009

JUN 26 2009

2. Device:

Trade Name: WallFlex Esophageal Fully Covered Stent System
Classification Name: Prosthesis, Esophageal
Regulation Number: 21 CFR 878.3610
Product Code: ESW
Classification: Class II

3. Predicate Device:

WallFlex Esophageal Partially Covered Stent System Manufactured by Boston Scientific, Inc.	K073266
ALIMAXX-E Esophageal Stent System Manufactured by Alveolus, Inc	K051621, K080838

4. Device Description:

The proposed WallFlex Esophageal Fully Covered Stent System consists of a self-expanding metal stent and a delivery system. The proposed stent is manufactured from a metallic radiopaque material that is formed into a cylindrical mesh. It is fully covered with a silicone polymer. A suture is threaded through the proximal end of the stent and is intended to aid in removal during the initial stent placement procedure, to be used in the event of incorrect placement. The delivery system is a coaxial tube design. The exterior tube is used to constrain the stent before deployment and reconstrain the stent, if desired, after partial deployment. The exterior tube has a clear section so that the contrained stent is visible. The interior tube has a single central lumen to accommodate a 0.038" guidewire.

5. Intended Use:

The WallFlex Esophageal Fully Covered Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by instrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistula.

6. Technological Characteristics:

The proposed WallFlex Esophageal Fully Covered Stent System is similar in design, materials, and manufacturing processes to the predicate devices, the WallFlex Esophageal

Partially Covered Stent System (K073266) and the ALIMAXX-E Esophageal Stent System (K051621, K080838).

7. Performance Data:

In-vitro testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed WallFlex Esophageal Fully Covered Stent System is substantially equivalent to the currently marketed WallFlex Esophageal Partially Covered Stent System (K073266) and the ALIMAXX-E Esophageal Stent System (K051621, K080838).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2009

Ms. Marybeth Gamber
Manager II, Regulatory Affairs
Boston Scientific Corporation
100 Boston Scientific Way
Endoscopy Division, M11
MARLBOROUGH MA 01752

Re: K091510
Trade/Device Name: WallFlex Esophageal Fully Covered Stent System
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: ESW
Dated: May 21, 2009
Received: May 27, 2009

Dear Ms. Gamber:

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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~This application~~ K091510

Device Name: WallFlex Esophageal Fully Covered Stent System

Indications for Use: The WallFlex Esophageal Fully Covered Stent System 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 K091510