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SECTION 5
510(K) SUMMARY

510(K) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4356
Fax: 508-683-5939

Contact: Allyson Barford, RAC
Regulatory Affairs Specialist
Date Prepared: September 13, 2006

2. Device:

Trade Name: WallFlex™ Enteral Duodenal Stent System with Anchor Lock Delivery System
Common Name: Esophageal prosthesis
Classification Name: Expandable, metallic duodenal stent
Regulation Number: 878.3610
Product Code: MUM
Classification: Class II

3. Predicate Device:

WallFlex™ Enteral Colonic Stent System with Anchor Lock Delivery System, K042065
Wallstent Enteral Endoprosthesis, K000281
The predicate devices are class II devices per 21 CFR 878.3610

4. Device Description:

The proposed WallFlex™ Enteral Duodenal Stent with Anchor Lock Delivery System consists of two components: an implantable metal stent and a delivery system. The proposed stent is manufactured of Nitinol and has a 22mm body diameter with a 27mm distal flare diameter, and is offered in three lengths, 6cm, 9cm, and 12cm. The Anchor Lock Delivery System consists of a coaxial tubing assembly that constrains the stent on the delivery catheter shaft until the stent is released by retracting the exterior tube.

5. Intended Use:

The proposed WallFlex™ Enteral Duodenal Stent is indicated for the palliative treatment of gastroduodenal obstructions caused by malignant neoplasms.

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6. Technological Characteristics:

The proposed WallFlex Enteral Duodenal Stent with Anchor Lock Delivery System has the identical technological (materials, construction, processing) characteristics as the predicate WallFlex Enteral Colonic Stent with Anchor Lock Delivery System and has the identical indication statement as the predicate Wallstent Enteral Endoprosthesis.

7. Performance Data:

Clinical data in support of the proposed indication for the WallFlex™ Enteral Duodenal Stent with Anchor Lock Delivery System has been included in this premarket notification.

8. Conclusion:

Boston Scientific Corporation has demonstrated that proposed WallFlex™ Enteral Duodenal Stent with Anchor Lock Delivery System is substantially equivalent to the currently marketed WallFlex™ Enteral Colonic Stent with Anchor Lock Delivery System and in terms of the proposed indication to Boston Scientific's Wallstent Enteral Endoprosthesis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

DEC - 4 2006

Ms. Allyson Barford
Regulatory Specialist
Boston Scientific Corporation
Endoscopy Division
100 Boston Scientific Way
MARLBOROUGH MA 01752

Re: K062750
Trade/Device Name: WallFlex Enteral Duodenal Stent with Anchor Lock Delivery System
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: MUM
Dated: September 13, 2006
Received: September 14, 2006

Dear Ms. Barford:

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 (Premarket Approval), 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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/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

K062750

SECTION 4
INDICATIONS FOR USE STATEMENT

Indications for Use:

510(k) Number (if known): ~~To Be Determined~~ K062750

Device Name: WallFlex Enteral Duodenal Stent with Anchor Lock Delivery System

Indications For Use:

The WallFlex™ Enteral Duodenal Stent with Anchor Lock Delivery System is indicated for the palliative treatment of gastroduodenal obstructions caused by malignant neoplasms.

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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062750