K042065

SEP 30 2004

Boston Scientific

Endoscopy

SECTION 10
510(K) SUMMARY

510(K) SUMMARY

1. Submitter:

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

Contact: Kathleen Morahan, RAC
Regulatory Affairs Manager
Date Prepared: July 30, 2004

2. Device:

Trade Name: WallFlex™ Enteral Colonic Stent with Anchor Lock Delivery System
Common Name: Expandable, metal colonic stent
Classification Name: Stent, colonic, metallic, expandable
Product Code: MQR
Classification: Class II

3. Predicate Device:

Boston Scientific Corporation's Ultraflex™ Precision™ Colonic Stent System, K030769.

Boston Scientific Corporation's Wallstent Enteral Endoprosthesis and Unistep Plus Delivery System, K000281.

4. Device Description:

The proposed WallFlex™ Enteral 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 offered in two diameters: 25mm body with a 30mm flare, and 22mm body with a 27mm flare. Each diameter is offered in three lengths, 6cm, 9cm, and 12cm. The proposed Anchor Lock delivery 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 Colonic Stent with Anchor Lock Delivery System is indicated for palliative treatment of colonic strictures caused by malignant neoplasms.

6. Technological Characteristics:

Essentially, the proposed WallFlex™ Enteral Colonic Stent with Anchor Lock Delivery System has the same technological characteristics as the predicate devices. The proposed stent combines the design features of the Ultraflex™ Precision™ Colonic stent and the Wallstent Enteral stent, yielding a self-expanding Nitinol stent. The proposed Anchor Lock delivery 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, like the predicate Wallstent Unistep Plus delivery system.

7. Performance Data:

Comparative performance testing was performed to establish substantial equivalence between the proposed WallFlex™ Enteral Colonic Stent with Anchor Lock Delivery System, and the predicate Ultraflex Precision Colonic Stent System, and the Wallstent Enteral Endoprothesis with Unistep Plus Delivery System. This testing included but was not limited to a dimensional evaluation, fatigue testing, radial force comparison, deployment and reconstrainment force, bond integrity and MRI.

8. Conclusion:

Boston Scientific Corporation has demonstrated that WallFlex Enteral Colonic Stent with Anchor Lock Delivery system is substantially equivalent to Boston Scientific Corporation's currently marketed Ultraflex™ Precision™ Colonic Stent and the Wallstent Enteral Endoprosthesis with Unistep Plus Delivery System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 2004

Ms. Kathleen Morahan
Regulatory Affairs Manager
Boston Scientific Corporation
Endoscopy Division
One Boston Scientific Place
NATICK MA 01760

Re: K042065
Trade/Device Name: WallFlex™ Enteral Colonic Stent and Anchor Lock Delivery System 25mm and 22mm x 90mm, -120mm, and -60mm
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: 78 MQR
Dated: July 30, 2004
Received: August 12, 2004

Dear Ms. Morahan:

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); 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

K042065

SECTION 3
INDICATIONS FOR USE

Indications for Use:

510(k) Number (if known): ~~To Be Determined~~ K042065

Device Name: WallFlex™ Enteral Colonic Stent with Anchor Lock Delivery System

Indications For Use:

The WallFlex™ Enteral Colonic Stent with Anchor Lock Delivery System is indicated for palliative treatment of colonic strictures 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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042065