Boston Scientific Corporation
August 7, 2006

SEP - 1 2006

SECTION 5
510(K) SUMMARY

510(K) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01760
Telephone: 508-683-4356
Fax: 508-683-5939

Contact: Allyson Barford, RAC
Regulatory Affairs Specialist
Date Prepared: August 7, 2006

2. Device:

Trade Name: WallFlex™ Biliary RX Uncovered Stent System
Common Name: Biliary Stent
Classification Name: Biliary Catheter and Accessories
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

3. Predicate Device:

Boston Scientific Corporation's Wallstent Biliary Endoprosthesis, K000308, K993232, K982184, K964119 and K925406

Boston Scientific Corporation's Wallstent RX Biliary Endoprosthesis, K012752 and K030107

The predicate devices are class II devices per 21 CFR 876.5010

4. Device Description:

The proposed WallFlex™ Biliary RX Uncovered Stent System consists of a self-expanding metal stent and a delivery catheter. The proposed stent consists of Platinum cored Nitinol wires wound together to form a cylinder with both proximal and distal flares. The proposed stent is mounted onto a sheath delivery system. The proposed delivery system is a coaxial tubing assembly that constrains the stent onto the delivery catheter shaft until the stent is released by retracting the exterior tube.

5. Intended Use:

The proposed WallFlex Biliary RX Uncovered Stent System is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms.

6. Technological Characteristics:

The proposed WallFlex Biliary RX Uncovered Stent System has similar technological characteristics to the currently marketed Wallstent Biliary Endoprosthesis (K000308, K993232, K982184, K964119 and K925406) and Wallstent RX Biliary Endoprosthesis (K012752 and K030107).

7. Performance Data:

Comparative performance testing was completed to establish substantial equivalence between the proposed WallFlex™ Biliary RX Uncovered Stent System and the predicate devices. This testing included but was not limited to dimensional evaluation, radial force, deployment and reconstrainment force and bond integrity.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed WallFlex Biliary RX Uncovered Stent System is substantially equivalent to Boston Scientific Corporation's currently marketed Wallstent RX Biliary Endoprosthesis and Wallstent Biliary Endoprosthesis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Allyson Barford, R.A.C.
Regulatory Affairs Specialist
Boston Scientific Corporation
Endoscopy
100 Boston Scientific Way
MARLBOROUGH MA 01752

SEP - 1 2006

Re: K061231
Trade/Device Name: WallFlex™ Biliary RX Uncovered Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: August 7, 2006
Received: August 8, 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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.

If you desire specific information about the application of other labeling requirements to your device (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" (21 CFR 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,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K061231

Device Name: WallFlex™ Biliary RX Uncovered Stent System

FDA's Statement of the Indications for Use for the device:

The WallFlex Biliary RX Uncovered Stent system is indicated for use in the palliative treatment of biliary strictures produced 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)

David R. Segger

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061231