OCT 2 3 2003

Boston Scientific

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
508.650.8000
www.bsci.com

510(K) Summary

1. Submitter:

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

Contact: Kathleen Morahan
Regulatory Affairs Manager
Date Prepared: September 17, 2003

2. Device:

Trade Name: Ultraflex™ Esophageal NG Stent System
Common Name: Esophageal Stent
Classification Name: Esophageal Prosthesis

3. Predicate Device:

BSC Ultraflex™ Esophageal Stent System – K955347

4. Device Description:

The proposed Ultraflex™ Esophageal NG Stent System consists of a self-expanding metal stent preloaded on a flexible delivery catheter. The stent is offered either bare or covered and with either a proximal release or distal release delivery system.

The stent may be placed flouroscopically using radiopaque markers as a guide or endoscopically using the visual marker on the delivery catheter. To deploy the stent, hold the handle hub in the palm of one hand, and grasp the finger ring with the other hand. As the finger ring is retracted, the suture crochet knots are unraveled in a circular manner along the length of the stent, gradually deploying the stent. When the stent is completely released, the delivery catheter is removed.

5. Intended Use:

The Ultraflex™ Esophageal NG Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and, for occlusion of concurrent esophageal fistula (for covered stents only).

6. Technological Characteristics:

The technological characteristics of the proposed and predicate devices are unchanged. The crochet suture pattern on the delivery catheter was modified to create a 10mm "visual marker" on the delivery system (for proximal release product codes only) to assist with endoscopic stent placement. The suture material threaded around the circumference of each stent end was also modified. These modifications have not impacted the device performance as demonstrated by bench testing.

7. Performance Data:

Bench testing was performed to aid with the establishment of substantial equivalence of the proposed device with the predicate device.

8. Conclusion:

BSC has demonstrated that the Ultraflex™ Esophageal NG Stent System is substantially equivalent to BSC's currently marketed Ultraflex™ Esophageal Stent System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 3 2003

Ms. Kathleen Morahan
Manager, Regulatory Affairs
Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
NATICK MA 01760-1537

Re: K032930
Trade/Device Name: Ultraflex™ Esophageal Next Generation (NG) Stent System Noncovered and Covered, Distal Release; Noncovered and Covered, Proximal Release
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: 79 ESW
Dated: September 18, 2003
Received: September 23, 2003

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

K032930

510(K) Number: ~~To Be Determined~~ K032930

Device Name: Ultraflex™ Esophageal NG Stent System

Indications for Use:

The Ultraflex™ Esophageal NG Stent System (non-covered) is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors only.

The Covered Ultraflex™ Esophageal NG Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors only, and occlusion of concurrent esophageal fistula.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.1091)
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032930