

K030769

JUL 14 2003

**Boston
Scientific**
MICROVASIVE

Microvasive Endoscopy
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
508-650-8000
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SECTION 11
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: March 10, 2003

2. Device:

Trade Name: Ultraflex™ Precision™ Colonic Stent System
Common Name: Expandable, metallic colonic stent
Classification Name: Not classified

3. Predicate Device:

C.R. Bard Memotherm® Colorectal Stent

4. Device Description:

The proposed Ultraflex™ Precision™ Colonic Stent System consists of a self-expanding metal stent and a delivery catheter. The proposed stent consists of Nitinol wires wound together to form a cylinder with a flared distal section. The proposed stent is mounted on a delivery catheter. The stent is compressed onto the tapered delivery catheter shaft and bound with braided nylon suture using a crochet stitch. The stent is deployed by holding the handle stationary and pulling a ring to unravel the crochet stitch.

6. Technological Characteristics:

The proposed Ultraflex™ Precision™ Colonic Stent System is a Nitinol, self-expanding stent mounted on a delivery catheter. The proposed stent diameter is 25mm along the body and 30mm at the flared distal section; the lengths are 6cm, 9cm, and 12cm.

The Ultraflex™ Precision™ Colonic Stent System is substantially equivalent to C.R. Bard's Memotherm Colorectal Stent. The devices have the same intended use and are both self-expanding stents constructed of Nitinol. Both stents are mounted on a delivery catheter, however the delivery catheter designs differ. The proposed Ultraflex™ Precision™ Colonic stent is bound onto the delivery catheter shaft with braided nylon suture using a crochet stitch. The predicate Memotherm Colorectal stent delivery catheter utilizes a co-axial tube and the stent is constrained onto the delivery catheter shaft by the outer sheath.

7. Performance Data:

The use of self-expanding metal stents for palliation of malignant colorectal strictures is well documented in the literature.

Comparative performance testing was performed, where appropriate, between the proposed Ultraflex Precision Colonic Stent System and the Bard Memotherm Colorectal Stent System to establish substantial equivalence. Additional performance data, such as tensile strength, fatigue, and corrosion resistance testing was also performed.

In vivo testing of the proposed Ultraflex Precision Colonic Stent System demonstrates that the device is safe and effective for its intended use.

8. Conclusion:

BSC has demonstrated that Ultraflex Precision Colonic Stent System is substantially equivalent to C.R. Bard's currently marketed Memotherm® Colorectal Stent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 2003

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

Re: K030769
Trade/Device Name: Ultraflex Precision
Colonic Stent System
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: 78 MQR
Dated: June 12, 2003
Received: June 16, 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.

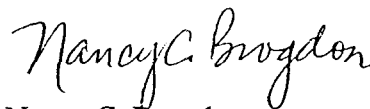
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 3
INDICATIONS FOR USE

510(k) Number: ~~To Be Determined~~ K030769

Device Name: Ultraflex™ Precision™ Colonic Stent

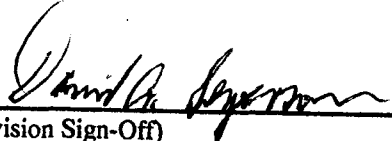
Indication for Use:

The Ultraflex™ Precision™ Colonic Stent is indicated for palliative treatment of colonic strictures in the descending colon, sigmoid colon and rectum caused by malignant neoplasms.

(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 K030769