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SEP 2 1 2006

510 (k) SUMMARY

SPONSOR:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

CONTACT PERSON:

Wing Ng
Regulatory Affairs Specialist
Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Tel: (508) 683-4141
Fax: (508) 683-5939
Date Prepared: June 23, 2006

DEVICE:

Trade Name: Maxforce TTS Single-Use Balloon Dilator
Common Name: Balloon Dilation Catheter
Classification: Class II, per 21 CFR Part 876, Section 5365

PREDICATE DEVICE: Boston Scientific Maxforce TTS Single-Use Balloon Dilator (K934697).

DEVICE DESCRIPTION: The Maxforce TTS Single-Use Balloon Dilator consists of a distal tip, balloon, catheter shaft, and proximal hub.

INTENDED USE: The Boston Scientific Corporation Maxforce TTS Single-Use Balloon Dilator is indicated for use in adults and adolescent populations to endoscopically dilate strictures of the esophagus.

DESCRIPTION OF CHANGE FOR THIS SUBMISSION:

The purpose of this premarket notification is to add four new contraindications to the Directions for Use of this device. The four new contraindications are as follows:

- Acute or incompletely healed perforation of the esophagus.
- Severe coagulopathy.

- Acute severe abdominal symptoms.
- Deeply ulcerated stenosis.

COMPARISON OF CHARACTERISTICS: The proposed device is substantially equivalent to the currently marketed device, as they have the same fundamental design, operating principal, materials, and intended use.

PERFORMANCE DATA: FDA's "Guidance for the Content of Premarket Notifications", and the results of physical comparison support a determination of substantial equivalence for the proposed device when compared to the predicate device.

SUBSTANTIAL EQUIVALENCE: The proposed Maxforce TTS Single-Use Balloon Dilator is substantially equivalent to the predicate Maxforce TTS Single-Use Balloon Dilator (K934697).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 21 2006

Mr. Wing Ng
Regulatory Affairs Specialist
Boston Scientific Corporation
Endoscopy
100 Boston Scientific Way
~~MARLBOROUGH MA~~ 01752

Re: K061787
Trade/Device Name: Maxforce TTS Single-Use Balloon Dilator
Regulation Number: 21 CFR §876.5365
Regulation Name: Esophageal dilator
Regulatory Class: II
Product Code: KNQ
Dated: August 22, 2006
Received: August 23, 2006

Dear Mr. Ng:

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

K061787

INDICATIONS FOR USE STATEMENT

510(k) Number To be determined

Device Name Maxforce TTS Single-Use Balloon Dilator

Indications For Use The proposed Maxforce TTS Single-Use Balloon Dilator is indicated for use in adults and adolescent populations to endoscopically dilate strictures of the esophagus.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X___ OR Over the Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

David A. Lagorm

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061787