

510 (k) SUMMARY

SPONSOR: Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

CONTACT PERSON: Paige K. Sweeney
Senior Regulatory Affairs Specialist

DEVICE:

Trade Name: Rigiflex™ II Single-Use Achalasia Balloon Dilator
Common Name: Balloon Dilatation Catheter
Classification: Class II, per 21 CFR Part 876, Section 5365

PREDICATE DEVICE: Boston Scientific Rigiflex™ Achalasia Balloon Dilator (K781772).

DESCRIPTION: The Rigiflex™ II Single-Use Achalasia Balloon Dilator consists of a balloon, catheter shaft, distal tip and proximal end.

INTENDED USE: The Boston Scientific Corporation Rigiflex™ II Single-Use Achalasia Balloon Dilator is indicated for dilatation of the cardia in patients with achalasia.

COMPARISON OF CHARACTERISTICS: The modified device is substantially equivalent to the currently marketed device, as they have the same operating principal and intended use. In addition, the results of design control activities do not raise any new issues of safety or effectiveness.

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

The modified device is substantially equivalent to the currently marketed Boston Scientific Rigiflex™ Achalasia Balloon Dilator in terms of performance characteristics, biocompatibility, and intended use.



MAR 11 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Paige Sweeney
Senior Regulatory Affairs Specialist
Endoscopy Division
Boston Scientific Corporation
One Boston Scientific Place
NATICK MA 01760-1537

Re: K050232
Trade/Device Name: Rigiflex™ II Single-Use Achalasia Balloon Dilator
Regulation Number: 21 CFR §876.5365
Regulation Name: Esophageal dilator
Regulatory Class: II
Product Code: 78 KNQ
Dated: February 10, 2005
Received: February 11, 2005

Dear Ms. Sweeney:

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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.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

Special 510(k) Premarket Notification
Rigiflex™ II Single-Use Achalasia Balloon Dilator

Boston Scientific Corporation
January 31, 2005

INDICATIONS FOR USE STATEMENT

510(k) Number ~~To be determined~~ K050232

Device Name Rigiflex™ II Single-Use Achalasia Balloon Dilator

Indications For Use The Boston Scientific Corporation Rigiflex™ II Single-Use Achalasia Balloon Dilator is indicated for dilatation of the cardia in patients with achalasia.

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

Nancy C. Brody
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050232