DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 9, 2014

Boston Scientific Corporation
Endoscopy Division
Paige Sweeney
Senior Regulatory Affairs Specialist
One Boston Scientific Place
Natick, MA 01760-1537

Re: K050232
Trade/Device Name: Rigiflex™ II Single-Use Achalasia Balloon Dilator
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PID
Dated (Date on orig SE ltr): February 10, 2005
Received (Date on orig SE ltr): February 11, 2005

Dear Paige Sweeney,

This letter corrects our substantially equivalent letter of March 11, 2005.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K050232

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 Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050232

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.