510(k) SUMMARY

OCT 24 2012

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4560
Fax: 508-683-5939

Contact: Janis F. Taranto, M.S., RAC
Regulatory Affairs Specialist
Date Prepared: September 21, 2012

2. Proposed Device:

Trade Name: CRE™ Balloon Dilatation Catheter
Classification Name: Dilator, Esophageal
Regulation Number: 876.5365
Product Code: KNQ
Classification: Class II

3. Predicate Device:

Trade Name: CRE™ Balloon Dilatation Catheter
Manufacturer and Clearance Number: Boston Scientific Corporation, K971320
Classification Name: Dilator, Esophageal
Regulation Number: 876. 5365
Product Code: KNQ
Classification: Class II

4. Proposed Device Description:

The proposed CRE™ Balloon Dilatation Catheter is capable of 3 distinct and progressively larger size diameters via controlled radial expansion. Specific balloon sizes are printed on each package and hub label. It is designed to be used through an endoscope having a 2.8mm or larger working channel. A stainless steel core wire extends through the entire length of the shaft. The wire is in tension within the balloon, which facilitates the removal of the catheter from the endoscope following balloon dilatation.

The proposed device incorporates a minor material formulation change for the flexible tip of the device.

5. Indication for Use:

The CRE™ Balloon Dilatation Catheter is intended for use in adult and adolescent populations to endoscopically dilate strictures of the esophagus.

6. Technological Characteristics:
The proposed CRE™ Balloon Dilatation Catheter is identical in design and manufacturing processes to the predicate CRE™ Balloon Dilatation Catheter (K971320) while incorporating a minor formulation change to the flexible tip.

7. Performance Data:
Biocompatibility of the proposed device was confirmed via AAMI/ANSI/ISO 10993-1: 2009, and included Cytotoxicity, Sensitization Intracutaneous Reactivity (Irritation),

In-vitro testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests including: chemical analysis, biocompatibility and tensile strength.

8. Conclusion:
Boston Scientific Corporation has demonstrated that the proposed Boston Scientific CRE™ Balloon Dilatation Catheter with minor device modifications is substantially equivalent to the predicate CRE™ Balloon Dilatation Catheter (K971320).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCT 2 4 2012

Ms. Janis F. Taranto
Regulatory Affairs Specialist
Boston Scientific Corporation
100 Boston Scientific Way
MARLBOROUGH MA 01752

Re: K122924
Trade/Device Name: CRE™ Balloon Dilatation Catheter
Regulation Number: 21 CFR§ 876.5365
Regulation Name: Esophageal dilator
Regulatory Class: II
Product Code: KNQ
Dated: September 21, 2012
Received: September 24, 2012

Dear Ms. Taranto:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

K122924

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K122924 ~~To Be Determined~~

Device Name: CRE™ Balloon Dilatation Catheter

Indications for Use: The CRE™ Balloon Dilatation Catheter is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the esophagus.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____ 000013
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122924