K112994
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FEB 10 2012

510(k) SUMMARY

1. Submitter

Boston Scientific Corporation
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Contact: Janis F. Taranto M.S., RAC
Regulatory Affairs Specialist
Date Prepared: October 9, 2011

2. Device

Trade Name: CRE Dilatation Balloon
Common Name: CRE Wireguided Dilatation Balloon
Classification Name: 1) Endoscope and/or accessories, 2) dilator, esophageal, 3) Catheter, Biliary, Diagnostic
Regulation Number: 1) 876.5010, 2) 876.5365, 3) 876.5010
Product Code: 1) KOG, 2) KNQ, 3) FGE
Classification: Class II

3. Predicate Devices

Trade Name: CRE Dilatation Balloon
Manufacturer and Clearance Number: Boston Scientific Corporation, K110833
Classification Name: 1) Endoscope and/or accessories, 2) dilator, esophageal
Regulation Number: 1) 876.5010, 2) 876.5365
Product Code: 1) KOG, 2) KNQ
Classification: Class II

Trade Name: Hurricane RX Biliary Balloon Dilatation Catheter
Manufacturer and Clearance Number: Boston Scientific Corporation K001338
Classification Name: Catheter, Biliary, Diagnostic
Regulation Number: 876.5010
Product Code: FGE
Classification: II

Trade Name: Maxforce Biliary
Manufacturer and Clearance Number: Boston Scientific Corporation, K910931
Classification Name: Catheter, Biliary, Diagnostic
Regulation Number: 876.5010
Product Code: FGE
Classification: II

4. Device Description

The CRE™ Wireguided 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.

The CRE™ Wireguided Balloon Dilatation Catheter is designed to pass through a 2.8mm or greater working channel of an endoscope and a 3.2 or 4.2 mm (depending on the balloon) or greater working channel of a duodenoscope. It will also accept a 0.035 in (0.89 mm) guidewire through its guidewire lumen. This catheter comes packaged with a 0.035 in (0.89 mm), floppy tip guidewire preloaded in the guidewire lumen. The guidewire is 25 cm longer than the balloon catheter with the excess length extending from the hub end of the catheter.

A guidewire locking device is attached to the guidewire hub of the catheter. The locking device will be packaged in the "OFF" or unlocked position. The guidewire may only be advanced or removed from the catheter when the switch on the locking device is in the "OFF" position. The guidewire may be held in place within the catheter by moving the switch to the "ON" position.

5. Indication for Use:

The CRE™ Wireguided Balloon Dilatation Catheter is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. It is also indicated in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomy.

6. Technological Characteristics:

The proposed CRE™ Wireguided Balloon Dilatation Catheter is identical in design, materials, and manufacturing processes to the predicate CRE™ Wireguided Balloon Dilatation Catheter (K110833).

7. Performance Data:

In-vitro testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests.

A clinical literature search was conducted and the resulting data supports the safety and effectiveness of the CRE™ Wireguided Balloon Dilatation Catheter for dilation of strictures of the biliary tree and the Sphincter of Oddi with or without prior sphincterotomy.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed CRE™ Wireguided Balloon Dilatation Catheter is substantially equivalent to Boston Scientific Corporation's currently marketed CRE™ Wireguided Balloon Dilatation Catheter (K110833), Hurricane RX Biliary Balloon Dilatation Catheter (K001338) and Maxforce Biliary Balloon Dilatation Catheter (K910931).

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

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Boston Scientific Corporation
Endoscopy
100 Boston Scientific Way
MARLBOROUGH MA 01752

FEB 10 2012

Re: K112994
Trade Name: CRE™ Wireguided Balloon Dilatation Catheter
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: February 9, 2012
Received: February 10, 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

INDICATIONS FOR USE

STATEMENT

510(k) Number (if known): K112994

Device Name: CRE™ Wireguided Balloon Dilatation Catheter

Indications for Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Part 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)

Carolyn J Neuland for Herb Lerner
(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112994