OCT 25 2011

510(k) Summary

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Submitter: Boston Scientific Corporation
One Scimed Place Maple Grove, MN 55311

Contact Person: Glenn Jacques
Phone Number: 763-494-1152
Fax Number: 763-494-2222
Date Prepared: September 15, 2011
Device Trade Name: Charger Balloon Dilatation Catheters
Common Name: Percutaneous Transluminal Angioplasty Dilatation Catheter
Device Classification: Class II 21 CFR 876.5010 Product Code: FGE

Predicate Devices
Mustang PTA Balloon Dilatation Catheters

Device Description
The Boston Scientific Charger™ Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheter is an over-the-wire (OTW) balloon catheter with a dual lumen shaft design. One lumen marked "WIRE" is used to pass the catheter over 0.035" (0.89mm) guidewires. The second lumen marked "BALLOON" communicates with the balloon and is used to inflate and deflate the balloon during the procedure. The guidewire lumen and the balloon lumen terminate at the proximal end of the catheter in a Y-connector manifold with luer lock fittings. There are two radiopaque marker bands located under the balloon shoulders to aid in positioning the system during the procedure. A coating is applied to the balloon to enhance insertion and withdrawal performance. The tip of the catheter is gradually tapered to facilitate advancement of the catheter through the stenosis.

The Charger™ Balloon Dilatation Catheter will be available with balloon diameters 3.0 mm to 12.0 mm, balloon lengths 20 mm to 200 mm and with shaft lengths of 40 cm, 75 cm, and 135 cm.

Indications for Use
The Charger Balloon Dilatation Catheters with balloons up to 120 mm in length are indicated for the treatment of biliary strictures.

Substantial Equivalence
The Charger PTA Balloon Dilatation Catheters design, materials, manufacturing process and intended use are substantially equivalent to the predicate device Mustang™ Balloon Dilatation Catheters (K110122).

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Comparison of Technological Characteristics

The Charger PTA Balloon Dilatation Catheter incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization processes and intended use as those featured in the Boston Scientific predicate device Mustang™ Balloon Dilatation Catheters (K110122).

Comparison to Predicate Devices in Materials and Manufacturing

Characteristic	Mustang predicate
Manifold	Same material. Different colorant. Same design serving same function
Strain Relief	Same material. Same design serving same function
Catheter Proximal Shaft / Distal Outer	Same material. Different colorant/additive. Same design serving same function
Catheter Inner Shaft	Same material, different colorant/additive and serving same function
Bumper Tip	Same material. Different colorant. Same design serving same function
Balloon	Same balloon material and design and serving same function and fundamental technology
Balloon Bonding Method	Same bonding method and function
Balloon Forming Process	Same forming method and function
Marker Bands	Same component serving same function
Coating	Same coating serving same function
Balloon Protector	Same material and similar design both serving same function.
Proximal Shaft Outer Diameter	Same shaft outer diameters

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Comparison to Predicate Devices Characteristics

Characteristic	Mustang predicate
Balloon Diameters	Same balloon diameter range serving same function
Balloon Lengths	Same balloon length ranges serving same function
Rated Burst Pressure (RBP)	Similar rated burst pressure
Catheter Length	Same catheter length ranges serving same function
Recommended Introducer Sheath Compatibility	Similar ranges and compatibilities
Recommended Guidewire	Same compatibility.
Sterilization Method	Same method.
SAL	Same level of assurance
Packaging Material and Configuration	Same design and function

Performance Data

Biocompatibility testing and bench testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing.

The following biocompatibility tests were completed on the Charger PTA Balloon Dilatation Catheter:

MEM Elution / Cytotoxicity
Guinea Pig Maximization Sensitization
Intracutaneous Reactivity
Acute Systemic Toxicity
Materials Mediated Rabbit Pyrogen
Hemolysis Direct Contact and Extract
Complement Activation
Partial Thromboplastin Time
In Vitro Hemocompatibility
Bacterial Mutagenicity (Ames Assay)
Mouse Lymphoma Assay
USP Physiochemical
Latex

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The following in-vitro performance tests were completed for the Charger PTA Balloon Dilatation Catheter as part of a Special 510k:

Bond Tensile

Conclusion

Based on the indications for use, technological characteristics, safety and performance testing, the Charger Balloon Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Boston Scientific Mustang™ Balloon Dilatation Catheters (K110122).

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. Glenn Jacques
Principal, Regulatory Affairs
Boston Scientific
One Scimed Place
MAPLE GROVE MN 55311

OCT 25 2011

Re: K112701
Trade/Device Name: Charger™ PTA Balloon Dilatation Catheters
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: September 21, 2011
Received: September 28, 2011

Dear Mr. Jacques:

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,

Herbert P. Lerner, M.D., Director (Acting)
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) K112701

Device Name **Charger™ PTA Balloon Dilatation Catheters**

Indications for Use Charger Balloon Dilatation Catheters with balloons up to 120 mm in length are indicated for the treatment of biliary strictures.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use____ (Per 21 CFR 801 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 K112701