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MAY 12 2011

510(k) Summary
per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Anne V. Rossi Manager, Regulatory Affairs Phone: 763-255-0681 Fax: 763-494-2222 e-mail: rossia@bsci.com
Date Prepared	14 January 2011
Proprietary Name	Mustang™ Balloon Dilatation Catheter
Common Name	Balloon Dilatation Catheter
Product Code	FGE
Classification	Class II, 21 CFR Part 876.5010
Predicate Device	SC 35 Balloon Dilatation Catheter K993303 23 March 2000
Device Description	The Boston Scientific Mustang™ Balloon Dilatation Catheter is an over-the-wire balloon catheter with a dual lumen shaft design. One lumen is used to pass the catheter over 0.035" guidewires. The second lumen 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 radiopaque marker bands located under the balloon to aid in positioning the system during the procedure. A silicone coating is applied to the balloon to enhance insertion and withdrawal performance. The Mustang™ Balloon Dilatation Catheter will be available with balloon diameters 3.0 mm to 12.0 mm, balloon lengths 2 cm to 12 cm and with shaft lengths of 40 cm, 75 cm, and 135 cm.
Intended Use of Device	The Mustang™ Balloon Dilatation Catheters are intended for dilatation of strictures in the biliary system.
Indications for Use	The Mustang Balloon Dilatation Catheters with balloons up to 120 mm in length are indicated for the treatment of biliary strictures.
Comparison of Technological Characteristics	The Mustang™ Balloon Dilatation Catheter incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the Boston Scientific predicate device, SC 35 Balloon Dilatation Catheter (K993303).

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Performance Data

Bench testing and biocompatibility 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 Mustang™ Balloon Dilatation Catheter:

Cytotoxicity	Direct Contact Hemolysis
Sensitization	Complement Activation
Intracutaneous Reactivity	Partial Thromboplastin Time
Acute Systemic Toxicity	In Vitro Hemocompatibility
Materials Mediated Pyrogenicity	Ames Mutagenicity
USP Physicochemical	Mouse Lymphoma Assays
Latex	

The following in-vitro performance tests were completed of the Mustang™ Balloon Dilatation Catheter:

Effective Length	Balloon Inflation/ Deflation Time
Shaft Outer Diameter	Device Tensile
Balloon Crossing Profile	Shaft Kink Resistance
Sheath Insertion and Withdrawal Force	Balloon Rated Burst Pressure in Stent
Balloon Rated Burst Pressure	Torque Strength
Balloon Fatigue	Balloon Fatigue in Stent
Balloon Compliance & Distension	Radiopacity
Coating Integrity	Particulate Evaluation

Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the Mustang™ Balloon Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Boston Scientific SC 35 Balloon Dilatation Catheter (K993303).

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MAY 12 2011

Mr. James M. Taufen
Regulatory Affairs Manager
Boston Scientific Corporation
One Scimed Place
MAPLE GROVE MN 55311-1566

Re: K110122
Trade/Device Name: Mustang™ Balloon Dilatation Catheter
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: May 5, 2011
Received: May 6, 2011

Dear Mr. Taufen:

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): K110122

Device Name Mustang™ Balloon Dilatation Catheter

Indications for Use

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

Prescription Use ____ OR Over-The-Counter Use ____
(Per 21 CFR 801 Subpart D) (21 CRF 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 K110122