

K103751

510(k) Summary
per 21 CFR §807.92

MAR 22 2011

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	22 December 2010		
Proprietary Name	Mustang™ Balloon Dilatation Catheter		
Common Name	PTA Balloon Dilatation Catheter		
Product Code	LIT, DQY		
Classification	Class II, 21 CFR Part 870.1250		
Predicate Devices	SC 35 Balloon Dilatation Catheter	K993305	10 April 2000
	Bard Dorado™ PTA Balloon Dilatation Catheter	K072283	19 September 2007
Device Description	<p>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.</p> <p>The Mustang™ Balloon Dilatation Catheter will be available with balloon diameters 3.0 mm to 12.0 mm, balloon lengths 2 cm to 20 cm and with shaft lengths of 40 cm, 75 cm, and 135 cm.</p>		
Intended Use of Device	<p>The Mustang™ Balloon Dilatation Catheter is intended for dilatation of stenosis in the peripheral vascular, for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae and post-deployed stent expansion of self-expanding and balloon expandable peripheral vascular stents.</p>		
Indications for Use	<p>The Mustang™ Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary arteries.</p> <p>The Mustang™ Balloon Dilatation Catheter is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.</p>		

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 (K993305). Mustang™ Balloon Dilatation Catheter incorporates similar design parameters and the same intended use as the Bard Dorado™ PTA Balloon Dilatation Catheter (K072283).

Comparison to Predicate Devices in Materials and Manufacturing

Mustang Characteristic	Synergy	Dorado
Manifold	Same material and design with minor dimensional differences but serving same function.	Unknown
Pinch-Off Tube	Same material, component and function.	Unknown
Strain Relief	Similar designs with same material serving same function.	Unknown
Proximal Dual Lumen Shaft	Same material and design serving same function.	Unknown
Distal Guidewire Lumen Shaft	Same design with minor difference in material but serving same function.	Unknown
Bumper Tip	Difference in design. Bumper tip is used in conjunction with the guidewire lumen to provide for a less stiff tip.	Unknown
Balloon	Difference in balloon material and design but serving same function and fundamental technology. The co-extruded design allows for the device to achieve high burst pressures.	Unknown
Balloon Bonding Method	Difference in bonding method but serving same function.	Unknown
Marker Bands	Same component serving same function.	Unknown
Coating	Different coating but serving same function. Silicone based coatings have history of use with BSC cleared PTA products.	Unknown
Balloon Protector	Same material and similar design both serving same function.	Unknown
Sterilization Method	Same method.	Unknown
SAL	Same level of assurance.	Unknown
Packaging	Similar design with the exception of the tray.	Unknown

Comparison of Technological Characteristics (Continued)

Comparison to Predicate Devices (Synergy and Dorado) Characteristics

Characteristic	Synergy	Dorado
Nominal Balloon Diameters	Same range serving same function.	Same range
Balloon Lengths	Similar range serving same function	Same range
Rated Burst Pressure (RBP)	Different balloon construction. Rated lower than Mustang, however, tested to meet rated pressures with 95% confidence on 99.9% population.	Same high pressure rated balloon
Effective Lengths	Similar ranges serving same function.	Same ranges
Recommended Introducer Sheath Compatibility	Similar ranges and compatibilities	Same ranges and compatibilities
Recommended Guidewire	Same compatibility.	Same compatibility

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 (K993305) and the Bard Dorado™ PTA Balloon Dilatation Catheter (K072283).



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

Boston Scientific Corporation
C/O Anne V. Rossi
Manager, Regulatory Affairs
One Scimed Place
Maple Grove, MN 55311

MAR 22 2011

Re: K103751

Trade/Device Name: Mustang™ Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: December 22, 2010
Received: December 23, 2010

Dear Ms. Anne Rossi:

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

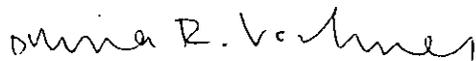
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comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing 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" (21 CFR 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,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103751

Device Name: Mustang™ Balloon Dilatation Catheter

Indications For Use:

The Mustang™ Balloon Dilatation Catheter is indicated for percutaneous transluminal angioplasty (PTA) in the peripheral vasculature including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary arteries.

The Mustang™ Balloon Dilatation Catheter is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Donna R. Vachner
(Division Sign-Off)
Division of Cardiovascular Devices

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