DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 22, 2014

Boston Scientific Corporation
Melanie Raska
Director, Regulatory Affairs
One Scimed Place
Maple Grove, MN 55311-1566

Re: K141597
Trade/Device Name: Mustang™ Balloon Dilation Catheter
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: August 5, 2014
Received: August 6, 2014

Dear Melanie Raska,

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 -S

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)	K141597
Device Name	**Mustang ™ PTA Balloon Dilatation Catheters**
Indications for Use	The Mustang ™ Balloon Dilatation Catheters with balloons up to 120mm 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)

510k 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	Elaine Ruddle Specialist , Regulatory Affairs Phone: +353 91 517936 Fax: 763-494-2222 e-mail: ruddlee@bsci.com **Or** Melanie Raska Director, Regulatory Affairs Phone :763-494 -2212 Fax: 763-494-2222 e-mail: raskam@bsci.com		
Date Prepared	June 12, 2014		
Proprietary Name	Mustang™ Balloon Dilatation Catheter		
Common Name	Percutaneous Transluminal Angioplasty Dilatation Catheter		
Product Code	FGE – Catheter, Biliary, Diagnostic		
Classification	Class II, 21 CFR Part 876.5010		
Predicate Device(s)	Mustang™ Balloon Dilatation Catheter	K110122	12 May 2011
	Gladiator Elite ™ Balloon Dilatation Catheter	K132810	28 February 2014
Device Description	Mustang Balloon Dilatation Catheters are over-the-wire balloon catheters 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.		
Intended Use of Device	The Mustang ™ Balloon Dilatation Catheter with balloons up to 120mm in length are indicated for the treatment of biliary strictures.		
Indications for Use	The Mustang ™ Balloon Dilatation Catheter with balloons up to 120mm in length are indicated for the treatment of biliary strictures.		

Comparison of Technological Characteristics

The Mustang Balloon Dilatation Catheter incorporates substantially equivalent device materials , design, catheter configuration, packaging fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the Boston Scientific predicate devices.

Comparison to predicate Devices :

Characteristic	Proposed compared to Predicates
Components	Same components, configuration, design and function
Materials	Same materials. Balloon contains an additional material not new to the device
Packaging	Same packaging materials and configuration
Sterilization Method /SAL	Same method and level of assurance
Guidewire compatibility	Same compatibility
Balloon Diameters and Lengths	Same sizes
Effective length	Same length catheters
Rated Burst Pressure (RBP)	Same RBP

Performance Data

Bench testing was 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 and therefore, these devices may be considered substantially equivalent to the predicate devices.

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

Balloon Compliance	Balloon Multiple Inflation
Balloon Nominal Diameter	Proximal Bond Tensile
Balloon Crossing Profile	Balloon Multiple Inflation in a Stent
Sheath Insertion and Withdrawal Force	Initial Sheath insertion Force
Balloon Rated Burst Pressure	Sheath Withdrawal
Balloon Burst Mode	Crossing Profile
Balloon Protector (Wingtool removal Force)	Burst in a stent

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 Mustang Balloon Dilatation Catheter and Gladiator Elite Balloon Dilatation Catheter.