DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 14, 2016

Boston Scientific Corporation
Ka Zoua Xiong
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K163200
Trade/Device Name: Maverick XL Percutaneous Transluminal Coronary Angioplasty Monorail Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II (Special Controls)
Product Code: LOX
Dated: November 14, 2016
Received: November 15, 2016

Dear Ka Zoua Xiong:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Brian D. Pullin -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163200

Device Name

Maverick™ XL Percutaneous Transluminal Coronary Angioplasty Monorail™ Dilatation Catheter

Indications for Use *(Describe)*

The Maverick XL balloon catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft for the purpose of improving myocardial perfusion. The Maverick XL balloon catheter is also indicated for the post delivery expansion of balloon expandable stents.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K163200

510(k) Summary

Per 21 CFR §807.92

Common or Usual Name	PTCA Dilatation Catheter	
Trade Name(s)	Maverick™ XL Percutaneous Transluminal Coronary Angioplasty Monorail™ Dilatation Catheter	
Product Code	LOX - Catheters, Transluminal Coronary Angioplasty, Percutaneous	
Classification of Device	Class II (special controls) - 21 CFR 870.5100	
Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311-1566	
Contact Name and Information	Ka Zoua Xiong Regulatory Affairs Specialist Phone: 763-494-2970 Fax: 763-494-2222 Email: Kazoua.Xiong@bsci.com	
Date Prepared	11 November 2016	
Section 514 of the Act Performance Standards	The special control for this device is FDA's "Class II Special Controls Guidance Document: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters"	
Establishment Registration Numbers	**Owner /Operator:**	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 ERN: 9912058
	Manufacturing Facility:	Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 ERN: 2134265
	Sterilization Facilities:	BSC Coventry 8 Industrial Drive Coventry, RI 02816 USA
Predicate Devices	P860019 - Maverick™ XL Percutaneous Transluminal Coronary Angioplasty Monorail™ Dilatation Catheter, date reclassified 08 October 2010	

Device Description	The Maverick XL Percutaneous Transluminal Coronary Angioplasty PTCA (Maverick XL) dilatation catheter is a Monorail catheter with a balloon near the distal tip. The distal catheter segment is dual lumen and coaxial, characteristic of all monorail style catheters. The balloon is located at the distal end of the catheter and is designed to provide an inflatable segment of known diameter and length at recommended pressures.
Intended Use/ Indications for Use	The Maverick XL balloon catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft for the purpose of improving myocardial perfusion. The Maverick XL balloon catheter is also indicated for the post delivery expansion of balloon expandable stents.
Comparison of Required Technological Characteristics	The proposed Maverick XL is substantially equivalent to the existing Maverick XL approved under premarket approval P860019, which have since been down-classified by FDA on 08Oct2010. Maverick XL has the same intended use, scientific technology, design (with the exception of the corewire design), materials, sterilization method, and packaging materials as the applicable predicate device.
Summary of Non-Clinical Test Summary	Bench testing and first article testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device with the modified corewire 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 device testing.
Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the proposed Maverick XL with the modified corewire has been shown to be appropriate for its intended use and is considered to be substantially equivalent to its predicate (P860019).