K134031

JUN 2 1 2014

510(k) Summary
per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation Cardiovascular Division One Scimed Place Maple Grove, MN 55311 Phone: 763-494-1700 Fax: 763-494-2222		
Contact Name and Information	Vicky L. Hagens Principal Regulatory Affairs Specialist Phone: 763-494-1522 Fax: 763-494-2222 e-mail: vicky.hagens@bsci.com		
Date Prepared	January 27, 2014		
Proprietary Name(s)	Threader™ Monorail™ Micro-Dilatation Catheter Threader™ Over-The-Wire Micro-Dilatation Catheter		
Common Name	Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheter		
Product Code	LOX		
Classification	Class II, 21 CFR Part 870.5100		
Predicate Devices	Emerge™ PTCA Dilatation Catheter (1.20 mm)	K130391	July 10, 2013
	CrossBoss™ Catheter	K102725	May 10, 2011
	Coyote™ PTA Balloon Dilatation Catheter	K111295	May 31, 2011
	Asahi Corsair Microcatheter	K083127	February 3, 2009
Device Description	The Boston Scientific Threader™ Micro-Dilatation Catheter is a sterile, single-use, intravascular medical device. The catheter consists of a shaft with a semi-compliant balloon near the distal tip. The balloon is designed to provide an inflatable segment of known diameter (1.2 mm) and length (12 mm) at recommended pressures. The Threader™ Micro-Dilatation Catheter is offered in both Monorail (MR) and Over-The-Wire (OTW) platforms. There is a single radiopaque marker band located in the center of the balloon body to aid in positioning the system during the procedure. Coatings are applied to the balloon and catheter to enhance insertion and withdrawal performance.		
Intended Use of Device	The Threader™ Micro-Dilatation Catheter is intended for dilatation of stenosis in coronary arteries or bypass grafts.		

Indications for Use	The Threader™ Micro-Dilatation Catheters are indicated for pre-dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis) for the purpose of improving myocardial perfusion. The Threader™ Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another. The Threader™ Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.
Comparison of Technological Characteristics	The Threader™ Micro-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 predicate devices: Emerge™ PTCA Dilatation Catheter (1.20 mm), K130391 (cleared July 10, 2013); CrossBoss™ Catheter, K102725 (cleared May 10, 2011); Coyote™ PTA Dilatation Catheter, K111295 (cleared May 31, 2011); and Asahi Corsair Microcatheter, K083127 (cleared February 3, 2009).
Performance Data	The Threader™ Micro-Dilatation Catheter was subjected to testing according to the requirements of *Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010. 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 and, therefore, these devices may be considered substantially equivalent to the predicate devices. The following biocompatibility and chemical characterization tests were completed on the Threader™ Micro-Dilatation Catheter: Cytotoxicity Sensitization Intracutaneous Reactivity Acute Systemic Toxicity Materials Mediated Pyrogenicity Hemolysis (Direct Contact & Extract) Complement Activation Coagulation In Vitro Hemocompatibility USP Physicochemical The following in-vitro performance tests were completed on the Threader™ Micro-Dilatation Catheter: Effective Length Shaft Inner and Outer Diameter Balloon Crossing Profile Balloon Preparation, Deployment, and Retraction Withdrawal into a Guide Catheter Balloon Rated Burst Pressure Balloon Fatigue (Repeat Inflations) Balloon Compliance Balloon Inflation/Deflation Time Catheter Bond Strength Tip Pull Test Flexibility and Kink Torque Strength Radiopacity Coating Integrity Particulate Evaluation Catheter Body Burst Pressure Contrast Media Flow Rate

Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the Threader™ Micro-Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the predicate devices.

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

July 21, 2014

Boston Scientific Corporation
Ms. Vicky Hagens
Principal Regulatory Affairs Specialist
One Scimed Place
Maple Grove, Minnesota 55311

Re: K134031
Trade/Device Name: Threader Monorail Micro-Dilatation Catheter, Threader Over-the-Wire Micro-Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: June 16, 2014
Received: June 17, 2014

Dear Ms. Hagens,

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 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. 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,

for 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): K134031

Device Name: Threader™ Monorail™ Micro-Dilatation Catheter
Threader™ Over-The-Wire Micro-Dilatation Catheter

Indications for Use:

The Threader Micro-Dilatation Catheters are indicated for pre-dilatation of the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis) for the purpose of improving myocardial perfusion.

The Threader Micro-Dilatation Catheters are intended to provide support to facilitate the placement of guidewires in the coronary vasculature. The Threader Over-The-Wire Micro-Dilatation Catheter can also be used to exchange one guidewire for another.

The Threader Over-The-Wire Micro-Dilatation Catheter is also intended to allow hand-injection of contrast media into the coronary vasculature.

Prescription Use X (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)

M A Hillebrenner