DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 14, 2016

Boston Scientific Corporation
Jane Horan
Senior Regulatory Affairs Specialist
Three Scimed Place
Maple Grove, Minnesota 55311

Re: K163174
Trade/Device Name: Emerge PTCA Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: November 10, 2016
Received: November 14, 2016

Dear Jane Horan:

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)*
K163174

Device Name
Emerge PTCA Dilatation Catheter

Indications for Use *(Describe)*
The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (1.20 mm balloon models) are indicated as pre-dilatation catheters in the stenotic portion of a coronary artery or bypass graft stenosis (≥70% stenosis).

The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (balloon models 1.50-4.00 mm) are indicated for the balloon catheter dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (balloon models 2.00-4.00 mm) are also indicated for the post-delivery expansion of balloon expandable stents (bare metal and drug-eluting).

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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510k Summary

Per 21 CFR §807.92

Common or Usual Name	PTCA Dilatation Catheter
Trade Name(s)	Emerge™ Monorail PTCA Dilatation Catheter Emerge™ Push Monorail PTCA Dilatation Catheter Emerge™ Over-The-Wire Monorail PTCA Dilatation Catheter Emerge™ Push Over-The-Wire Monorail PTCA Dilatation Catheter
Product Code	LOX – Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Classification of Device	Class II, 21 CFR 870.5100
Submitter's Name and Address	Boston Scientific Corporation Three Scimed Place Maple Grove, MN 55311-1566
Contact Name and Information	Jane Horan Senior Regulatory Affairs Specialist Phone: 763-494-2572 Fax: 763-494-2222 Email: Jane.Horan@bsci.com
Date Prepared	7 Dec. 2016
Section 514 of the Act Performance Standards	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for percutaneous 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:	Boston Scientific Corporation – Coventry 8 Industrial Drive Coventry, RI 02816 ERN: 1000121056
		STERIS Isomedix Services 3459 South Clinton Avenue South Plainfield, NJ 07080 ERN: 2246552
		Synergy Health Ireland Ltd. (Tullamore) IDA Business & Technology Park Tullamore, County Offaly Ireland ERN: 3002807314
		Synergy Health AST, SRL B13. 1 Street 4, Avenue 1 El Coyol Free Zone El Coyol, Alajeula 20102 Costa Rica ERN: 3010273872
		Synergy Health Venlo Faunalaan 38 Venlo Limburg, Netherlands 5928 RZ ERN: 3009337401

Predicate Devices	Emerge™ PTCA Dilatation Catheter, K113220, cleared 22 March 2012. Emerge™ PTCA Dilatation Catheter, K121196, cleared 31 August 2012. Emerge™ PTCA Dilatation Catheter, K130391, cleared 10 July 2013.
Reference Device	NC Emerge™ PTCA Dilatation Catheter, K141236, cleared 7 August 2014
Device Description	The Boston Scientific Emerge™ PTCA Dilatation Catheter is a sterile (EO), single-use, intravascular medical device for use in coronary angioplasty procedures. The catheter consists of a dual-lumen polymeric shaft with a balloon near the distal tip. The outer lumen is used for inflation of the balloon, and the inner lumen permits the use of a guidewire to facilitate advancement of the catheter to the appropriate location. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The Emerge™ PTCA Dilatation Catheter is offered in both Monorail (MR) and Over-The-Wire (OTW) platforms. Marks on the proximal portion of the catheter shaft (at 90 cm and 100 cm) indicate the exit of the balloon catheter tip out of the guide catheter. Radiopaque marker bands located under the balloon aid in positioning the system during the procedure. Hydrophilic and hydrophobic coatings are applied to the balloon and catheter to enhance insertion and withdrawal performance. The Emerge™ PTCA Dilatation Catheters (1.20 mm and 1.50 mm balloon models) are available in balloon lengths from 8 mm to 20 mm. The Emerge™ PTCA Dilatation Catheters (2.00 - 4.00 mm balloon models) are available in balloon lengths from 8 mm to 30 mm.

Intended Use/ Indications for Use	The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (1.20 mm balloon models) are indicated as pre-dilatation catheters in the stenotic portion of a coronary artery or bypass graft stenosis (≥ 70% stenosis). The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (balloon models 1.50-4.00 mm) are indicated for the balloon catheter dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (balloon models 2.00 - 4.00 mm) are also indicated for the post-delivery expansion of balloon expandable stents (bare metal and drug-eluting).
Comparison of Required Technological Characteristics	The proposed Emerge™ PTCA 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 devices, Emerge™ PTCA Dilatation Catheter K113220 (cleared March 22, 2012); Emerge™ PTCA Dilatation Catheter K121196 (cleared August 31, 2012); and Emerge™ PTCA Dilatation Catheter K130391 (cleared July 10, 2013). The proposed and predicate devices share the following technological characteristics: • Fundamental catheter design and intended use • Shaft, balloon, marker band, and coating materials • Packaging materials and design • Sterilization method • Fundamental manufacturing processes The proposed and predicate devices differ in the following technological characteristic: • Method of making proximal marks on the shaft

Summary of Non-Clinical Test Summary

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 device testing.

The following performance tests were completed on the Emerge™ PTCA Dilatation Catheter:

Corrosion Resistance	Proximal Mark Abrasion Resistance
Proximal Shaft Marks	Repeat Inflation
Midshaft Bond Tensile	Shaft and Bond Burst Pressure

The following biocompatibility and chemical characterization tests were completed on the Emerge™ PTCA Dilatation Catheter:

Cytotoxicity	Partial Thromboplastin Time
Sensitization	In Vitro Hemocompatibility
Intracutaneous Reactivity	Complement Activation
Acute Systemic Injection	USP Physicochemical
Materials Mediated Pyrogenicity	Latex Assay
Mutagenicity	Nonvolatile Residue
Hemolysis	SEM

Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the proposed Emerge™ PTCA Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to Emerge™ PTCA Dilatation Catheter (K113220), (K121196) and (K130391).