DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 7, 2014

Boston Scientific Corporation
c/o Ms. Adrienne Hotchkiss
Senior Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K141236
Trade/Device Name: NC Emerge™ PTCA Dilatation Catheter (Monorail and Over-the-Wire)
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: May 13, 2014
Received: May 14, 2014

Dear Ms. Hotchkiss:

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" (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 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 yours,

Fernando Aguel -S

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): K141236

Device Name: NC Emerge™ Monorail™ PTCA Dilatation Catheter
NC Emerge™ Over-The-Wire PTCA Dilatation Catheter

Indications for Use:

The NC Emerge Over-The-Wire (OTW) and NC Emerge Monorail (MR) PTCA Dilatation Catheters are indicated for the balloon catheter dilatation of the stenotic portion of a native coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion in patients with atherosclerosis.

NC Emerge Over-The-Wire and NC Emerge Monorail PTCA Dilatation Catheters (balloon models 2.00-5.00 mm) are also indicated for the post-delivery expansion of balloon expandable stents (bare metal and drug-eluting).

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)

Fernando Aguel -S

510(k) Summary
per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation Interventional Cardiology Division One Scimed Place Maple Grove, MN 55311 Phone: 763-494-1700 Fax: 763-494-2222		
Contact Name and Information	Adrienne Hotchkiss Senior Regulatory Affairs Specialist Phone: 763-494-1588 Fax: 763-494-2222 e-mail: hotchkia@bsci.com		
Date Prepared	09 May 2014		
Proprietary Name(s)	NC Emerge™ Monorail™ PTCA Dilatation Catheter NC Emerge™ Over-The-Wire PTCA 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 (2.00 – 4.00 mm diameter Monorail and Over-the-Wire balloon models)	K113220	22 March 2012
	NC Quantum Apex™ PTCA Dilatation Catheter (Monorail)	K121667	18 August 2012
	NC Quantum Apex™ PTCA Dilatation Catheter (Over-the-Wire)	P860019/S241 (Prior to reclassification of Balloon Angioplasty Catheters from Class III to Class II with special controls	16 April 2010
	Maverick™ XL PTCA Dilatation Catheter (Monorail)	P860019/S183 (Prior to reclassification of Balloon Angioplasty Catheters from Class III to Class II with special controls)	24 October 2002

Device Description

The NC Emerge PTCA Dilatation Catheters are sterile, single-use, intravascular medical devices. The catheter consists of a shaft with a balloon near the distal tip. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The NC Emerge PTCA Dilatation Catheter is offered in both Monorail (MR) and Over-The-Wire (OTW) platforms. There are two (2) radiopaque marker bands located under the balloon to aid in positioning the system during the procedure. Coatings are applied to the balloon and catheter to enhance insertion and withdrawal performance.

The NC Emerge PTCA Dilatation Catheter will be available in select combinations of 2.0-6.0mm diameters and 6-30mm lengths as shown below:

		Length (mm)					
		6	8	12	15	20	30
Width (mm)	2.00	X	X	X	X	X	X
	2.25	X	X	X	X	X	X
	2.50	X	X	X	X	X	X
	2.75	X	X	X	X	X	X
	3.00	X	X	X	X	X	X
	3.25	X	X	X	X	X	X
	3.50	X	X	X	X	X	X
	3.75	X	X	X	X	X	X
	4.00	X	X	X	X	X	X
	4.50	X	X	X	X	X	
	5.00	X	X	X	X	X	
	5.50		X	X	X	X	
	6.00		X	X	X	X	

Intended Use of Device

The NC Emerge PTCA Dilatation Catheters are intended to enable dilation of stenotic small and large lumen coronary vessels.

Indications for Use

The NC Emerge Monorail (MR) and NC Emerge Over-The-Wire (OTW) PTCA Dilatation Catheters are indicated for the balloon catheter dilatation of the stenotic portion of a native coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion in patients with atherosclerosis.

NC Emerge Over-The-Wire and NC Emerge Monorail PTCA Dilatation Catheters (balloon models 2.00-5.00 mm) are also indicated for the post-delivery expansion of balloon expandable stents (bare metal and drug-eluting).

Substantial Equivalence / Comparison of Technological Characteristics

The NC Emerge PTCA Dilatation Catheters incorporate 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 Catheters (K113220), NC Quantum Apex PTCA Dilatation Catheters (K121667 and P860019/S241), and Maverick XL PTCA Dilatation Catheters (P860019/S183).

Performance Data

The NC Emerge PTCA 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*, 08 September 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 NC Emerge PTCA Dilatation Catheters:

Cytotoxicity	Hemolysis (Direct Contact)
Sensitization	Hemolysis (Extract Method)
Intracutaneous Reactivity	Complement Activation
Acute Systemic Toxicity	Coagulation
Materials Mediated Pyrogenicity	In Vitro Hemocompatibility
USP Physicochemical	

The following in-vitro performance tests were completed and support the NC Emerge PTCA Dilatation Catheters:

Effective Length	Tip Pull Test
Shaft Inner and Outer Diameter	Flexibility and Kink
Crossing Profile	Torque Strength
Balloon Preparation, Deployment, and Retraction	Radiopacity
Withdrawal into a Guide Catheter	Coating Integrity
Rated Burst Pressure	Particulate Evaluation
Balloon Fatigue (Repeat Inflations)	Rated Burst Pressure in a Stent
Balloon Compliance	Balloon Fatigue (in Stent)
Balloon Inflation/Deflation Time	Kissing Balloon Compatibility
Catheter Bond Strength Tensile	

Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the NC Emerge PTCA Dilatation Catheters have been shown to be appropriate for their intended use and are considered to be substantially equivalent to the Boston Scientific predicate device Emerge PTCA Dilatation Catheters (2.00 – 4.00 mm diameter) (K121667), NC Quantum Apex PTCA Dilatation Catheters (K121667 and P860019/S41), and Maverick XL PTCA Dilatation Catheters (P860019/S183).