



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 23, 2016

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

Re: K160823

Trade/Device Name: NC Quantum Apex 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: May 23, 2016
Received: May 24, 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 yours,

Kenneth J. Cavanaugh -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): K160823

Device Name:

NC Quantum Apex™ PTCA Dilatation Catheter

Indications for Use:

NC Quantum Apex 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. NC Quantum Apex PTCA Dilatation Catheters are also indicated for the post-delivery expansion of balloon expandable stents (bare metal and drug-eluting).

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

510k Summary
Per 21 CFR §807.92

Common or Usual Name	PTCA Dilatation Catheter	
Trade Name(s)	NC Quantum Apex™ 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 One 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	01 May 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

Sterilization Facilities:	<hr/> <p>STERIS Isomedix Services 3459 South Clinton Avenue South Plainfield, NJ 07080 ERN: 2246552</p> <hr/> <p>Synergy Health Ireland Ltd. (Tullamore) IDA Business & Technology Park Tullamore, County Offaly Ireland ERN: 3002807314</p> <hr/> <p>Synergy Health AST, SRL B13. 1 Street 4, Avenue 1 El Coyol Free Zone El Coyol, Alajuela 20102 Costa Rica ERN: 3010273872</p> <hr/> <p>Synergy Health Venlo Faunalaan 38 Venlo Limburg, Netherlands 5928 RZ ERN: 3009337401</p> <hr/>
Predicate Device	<hr/> <p>NC Quantum Apex™ PTCA Dilatation Catheter, K121667, cleared 13 August 2012.</p> <hr/>
Reference Device	<hr/> <p>NC Emerge™ PTCA Dilatation Catheter, K141236, cleared 7 August 2014</p> <hr/>
Intended Use/ Indications for Use	<hr/> <p>NC Quantum Apex™ 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. NC Quantum Apex™ PTCA Dilatation Catheters are also indicated for the post-delivery expansion of balloon expandable stents (bare metal and drug-eluting).</p> <hr/>
Comparison of Required Technological Characteristics	<hr/> <p>The proposed NC Quantum Apex™ PTCA Dilatation Catheter is substantially equivalent to the existing NC Quantum Apex™ PTCA Dilatation Catheter cleared by FDA under premarket notification K121667 (August 13, 2012). NC Quantum Apex™ has the same intended use, scientific technology, design, sterilization method, packaging materials, and equivalent materials as the applicable predicate device.</p> <hr/>

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 NC Quantum Apex™ 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 NC Quantum Apex™ 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 NC Quantum Apex™ PTCA Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the NC Quantum Apex™ PTCA Dilatation Catheter (K121667).