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 25, 2017

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

Re: K171913
Trade/Device Name: Rubicon 14, 18 and 35 Support Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: June 22, 2017
Received: June 26, 2017

Dear Ms. 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,

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

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)*
K171913

Device Name
Rubicon™ 14, 18 and 35 Support Catheters

Indications for Use *(Describe)*
The Rubicon Support Catheter is intended to facilitate placement and support of guidewires and other interventional devices within the peripheral vasculature and to allow for exchange of guidewires, and provide a conduit for the delivery of saline or contrast solutions.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Per 21 CFR §807.92

Common or Usual Name	Percutaneous Catheter
Trade Name(s)	Rubicon™ 14, 18 and 35 Support Catheters
Product Code	DQY - Percutaneous Catheter
Classification of Device	Class II - 21 CFR 870.1250
Submitter's Name and Address	Boston Scientific Corporation Three Scimed Place, C275 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	22 June 2017
Section 514 of the Act Performance Standards	**6-301: ISO 10555-1 Second edition 2013-06-15** *Intravascular catheters -- Sterile and single-use intravascular catheters -- Part 1: General requirements* **6-322: ISO 10555-4 Second edition 2013-06-15** *Intravascular catheters -- Sterile and single-use catheters -- Part 4: Balloon dilatation 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	K112303 - Rubicon™ 14 Support Catheter K122394 - Rubicon™ 18 Support Catheter Rubicon™ 35 Support Catheter

Device Description	The Rubicon™ 14, 18 and 35 Support Catheters (Rubicon) are multipurpose intravascular device that can be used for wire exchanges, saline or contrast injection and to support a guidewire or other devices to cross peripheral lesions. They are available in 65cm, 90cm, 135cm, and 150cm shaft lengths. To use the Rubicon Support Catheter, the physician backloads the distal tip of the support catheter over a pre-positioned guidewire, ensuring the guidewire exits the proximal hub/luer and advances the support catheter to the target area. The Rubicon Support Catheter may also be introduced through a previously positioned, appropriately sized introducer sheath or guide sheath/catheter, advancing the Rubicon Support Catheter to its desired location while using fluoroscopic imaging.
Intended Use/ Indications for Use	The Rubicon Support Catheter is intended to facilitate placement and support of guidewires and other interventional devices within the peripheral vasculature and to allow for exchange of guidewires, and provide a conduit for the delivery of saline or contrast solutions.
Comparison of Required Technological Characteristics	Rubicon is substantially equivalent to the existing Rubicon devices cleared by FDA under Premarket Notifications K112303 and K122394 (09 Nov 2011 and 30 Aug 2012, respectively). Rubicon has the same intended use, scientific technology, design, materials, and sterilization method. The packaging dimensions and pouch materials were modified as compared to the applicable predicate devices.

Non-Clinical Test Summary

The following bench testing were performed to support a determination of substantial equivalence:

- Pouch Seal Strength
- Catheter Withdrawal from the Carrier Tube
- Angle Clip Retention
- Angled Clip Removal
- Pouch Sterile Barrier Integrity - Bubble
- Pouch Sterile Barrier Integrity – Visual
- Shelf Carton Condition
- Master Shipping Carton Condition
- Label Adhesion and Print Quality

The results of these tests provide reasonable assurance that the proposed packaging modifications have been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during bench testing.

The proposed packaging changes did not require new biocompatibility or device bench testing to support substantial equivalence. Therefore, testing results from the predicate devices still apply.

Clinical Testing

Clinical evaluation was not required to support a determination of substantial equivalence.

Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the proposed Rubicon™ 14, 18 and 35 Support Catheters have been shown to be appropriate for its intended use and are considered to be substantially equivalent to their respective predicates (K112303 and K122394).