510(k) Summary
per 21 CFR §807.92

AUG 30 2012

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Diane Nelson Regulatory Affairs Specialist Phone: 763-255-0813 Fax: 763-494-2222 e-mail: diane.nelson@bsci.com
Date Prepared	06 August 2012
Proprietary Name	Boston Scientific Rubicon™ 18 Support Catheter Boston Scientific Rubicon™ 35 Support Catheter
Common Name	Percutaneous Catheter
Product Code	DQY
Classification	Class II, 21 CFR Part 870.1250
Predicate Device	Boston Scientific Corporation K112303 09 November 2011 Rubicon™ 14 Support Catheter
Device Description	The Boston Scientific Rubicon Support Catheters feature an ultra low profile tip, a lubricious hydrophilic coating that is applied to the surface of the distal 40 cm of the catheter, and 3 radiopaque markers spaced equally along the distal shaft which aid in estimating geometry within the vascular system. The distal radiopaque marker is positioned approximately 2mm away from the distal catheter tip. The proximal portion of the catheter includes one female luer-lock port connected to the proximal end of the catheter for guidewire entry and fluid injection.
Intended Use of Device	The Rubicon Support Catheters are multipurpose intravascular devices that can be used for wire exchanges, saline, contrast injection and to support a guidewire or other CTO (Chronic Total Occlusion) devices. The Support Catheter can be back loaded over a pre-positioned guidewire or may be introduced through a previously positioned appropriately sized introducer sheath and advanced to the targeted area of the lesion. The guidewire is advanced through the lesion and the support catheter is advanced over the wire until the guidewire exits the lesion and the Support Catheter reaches the patent lumen of the vessel.
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 Technological Characteristics

Rubicon 18 Support Catheter and Rubicon 35 Support Catheter incorporate substantially equivalent device design and materials, packaging design and materials, fundamental technology, manufacturing processes, sterilization process, and intended use as those featured in the predicate device, Boston Scientific Rubicon 14 Support Catheter (K112303).

Performance Data

Biocompatibility testing was completed and submitted as part of the Rubicon 14 Support Catheter (K112303). The Rubicon 18 and 35 Support Catheters are equivalent in design, materials, and manufacturing to the Rubicon 14 Support Catheter, cleared by the FDA November 9, 2011. Since no changes have been implemented that would affect the biocompatibility of the devices, these results are applicable to the subject devices.

Biocompatibility tests were leveraged from predicate Rubicon 14:

MEM Elution Cytotoxicity	Hemolysis Assay Indirect Extraction
Guinea Pig (Maximization) Sensitization	Partial Thromboplastin Time
Intracutaneous Reactivity	In Vitro Hemocompatibility Assay
Systemic Toxicity (Acute)	Complement Activation
Materials Mediated Rabbit Pyrogen	USP Physicochemical
Hemolysis Assay Direct Contact	Natural Rubber Latex

The following in-vitro performance bench tests confirm the performance characteristics:

Effective Length	Sheath Insertion and Withdrawal Force
Inner Diameter – Distal Shaft	Catheter Shaft Burst Pressure
Outer Diameter – Proximal Shaft	Catheter Tensile
Outer Diameter – Distal Shaft	Shaft Kink Resistance
Marker Band Spacing	Torque Strength
Contrast Flow Rate	Radiopacity
Flow rates for DFU labeling	Coating Integrity

All test results demonstrate that the materials, manufacturing process, and design of the Rubicon 18 and 35 Support Catheters meet the established specifications necessary for consistent performance according to its intended use.

Conclusion

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 30 2012

Boston Scientific Corp.
% Diane Nelson
One Scimed Place
Maple Grove, MN 55311-1566

Re: K122394
Trade/Device Name: Rubicon 18 and 35 Support Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 6, 2012
Received: August 7, 2012

Dear Ms. Nelson:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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 Statement

510(k) Number (if known) K122394

Device Name: Rubicon™ Support Catheters

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.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122394