August 8, 2023

Boston Scientific Corporation
Mary-Jo Foley
Principal Regulatory Affairs Specialist
One Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K223633
Trade/Device Name: Rubicon™ Control Support Catheter (H749394323506A1)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 28, 2023
Received: July 28, 2023

Dear Mary-Jo Foley:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Samuel G. Raben -S

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K223633

Device Name

Rubicon™ Control Support Catheter

Indications for Use *(Describe)*

Rubicon Control 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.

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Rubicon Control Support Catheter 510(k) Summary

I. SUBMITTER

Boston Scientific Corporation
One Scimed Place
Maple Grove,
MN 55311-1566
USA
Contact Person: Mary-Jo Foley
Date Prepared: December 5th, 2022

II. DEVICE

Name of Device: Rubicon™ Control Support Catheter
Common or Usual Name: Support Catheter
Classification Name: Percutaneous Catheter (21 CFR 870.1250)
Regulatory Class: II
Product Code: DQY

III. PREDICATE DEVICE

Rubicon Support Catheter, K171913
This predicate has not been subject to a design-related recall.

Reference device:
EMERGE™ Monorail™ Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheter, K220629.

IV. DEVICE DESCRIPTION

The Rubicon™ Control Support Catheter is a sterile, single use, single lumen, over the wire (OTW) device designed for use in the peripheral vasculature. The catheter is designed to facilitate placement and support of guidewires and other interventional devices, to allow for exchange of guidewires and provide a conduit for the delivery of saline or contrast solutions. The shaft design is a tri-layer extrusion with a braided middle layer. There are three (3) radiopaque markerbands spaced equally along the distal shaft. The distal most markerband is approximately 2 mm away from the distal end of the catheter tip to aid in positioning the system during the procedure. The distal 40 cm portion of the catheter is coated with a hydrophilic coating to aid device insertion through the guide sheath or guide catheter. The catheter is available with a straight tip and an angled tip. The catheter is available in shaft lengths 65 cm, 90 cm, 135 cm, and 150 cm compatible with 0.014'' (0.356 mm), 0.018'' (0.457 mm), and 0.035'' (0.889 mm) guidewires. The 0.035" support catheter is compatible with 5Fr sheath; the 0.014" and 0.018" are compatible with 4Fr sheath.

There are no accessories supplied with the device.

V. INDICATIONS FOR USE

Rubicon Control 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Rubicon Control Support Catheter has the same indication for use, principle of operation, sterilization method, delivery system lengths and device compatibility as the predicate Rubicon Support Catheter (K171913).

The following technological differences exist between the subject and predicate devices:

- Availability of straight and angled tip configuration to aid vessel navigation
- Braided shaft design for added guidewire support

Differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. The results of bench testing provide reasonable assurance of substantial equivalence of the Rubicon Control Support Catheter with the predicate device.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation was conducted to ensure that the Rubicon Control Support Catheter meets the recommended biocompatibility endpoints as outlined in ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management process and FDA Guidance – Use of International Standard ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management process (September 4th, 2020). The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Hemolysis
- Pyrogen Testing

The device is categorized as externally communicating, limited contact (<24 hours), circulating blood contacting.

Mechanical testing

- Simulated use testing
- Catheter Bond Strength
- Catheter Body Burst Pressure
- Contrast Flow Rate
- Tip Pull Test
- Torque Strength
- Particulate Evaluation
- Coating Integrity

- Shelf Life and Packaging

VIII. CONCLUSIONS

The subject and predicate devices share the same indications for use and fundamental scientific technology, including principle of operation. Differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. Non-clinical performance evaluations support substantial equivalence of the Rubicon Control Support Catheter to the predicate Rubicon Support Catheter (K171913).