July 10, 2024

Boston Scientific Corporation
Michael Mcdonagh
Fellow Regulatory Specialist
Two Scimed Place
Maple Grove, Minnesota 55311

Re: K241683
Trade/Device Name: Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031404020, H74939031406020, H74939031408020, H74939031410020, H74939031412020, H74939031415020, H74939031420020, H74939031504020, H74939031506020, H74939031508020, H74939031510020, H74939031512020, H74939031515020, H74939031520020, H74939031604020, H74939031606020, H74939031608020, H74939031610020, H74939031612020, H74939031615020, H74939031620020, H74939031704020, H74939031706020, H74939031708020, H74939031710020, H74939031712020, H74939031715020, H74939031720020)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: June 11, 2024
Received: June 11, 2024

Dear Michael Mcdonagh:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2024.07.10 16:56:10 -04'00'

For

Gregory O'Connell
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241683

Device Name

Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031404020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031406020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031408020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031410020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031412020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031415020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031420020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031504020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031506020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031508020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031510020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031512020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031515020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031520020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031604020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031606020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031608020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031610020);
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Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031615020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031620020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031704020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031706020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031708020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031710020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031712020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031715020);
Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031720020)

Indications for Use *(Describe)*

The Sterling Monorail PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal, renal, and carotid arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

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.

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510(k) Summary

1. Submitter

Boston Scientific Corporation

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United States

Contact Person: Michael McDonagh

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Ballybrit Business Park, Galway, Ireland

Date Prepared: June 11, 2024

2. Device

Name of Device:

Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031404020);

Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031406020);

Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031408020);

Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031410020);

Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031412020);

Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031415020);

Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031420020);

Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031504020);

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Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031604020);

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Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031712020);

Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031715020);

Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (H74939031720020)

Common or Usual Name: Percutaneous Catheter

Classification Name: Catheter, Angioplasty, Peripheral, Transluminal

Regulatory Class: II

Product Code: LIT

3. Predicate Device

Predicate Device: Sterling™ MONORAIL™ PTA Balloon Dilatation Catheter (K162350)

Reference Devices: Sterling™ OVER-THE-WIRE PTA Balloon Dilatation Catheter (K141112, K132430, K053116); Sterling™ SL OVER-THE-WIRE PTA Balloon Dilatation Catheter (K093720)

4. Device Description

The Sterling Balloon Dilatation Catheter is a Monorail brand rapid exchange catheter with a semi-compliant balloon fixed at the distal tip. The balloon catheter has a coaxial shaft design. The outer lumen is used for inflation of the balloon, and the wire lumen permits the use of guidewires 0.014 in / 0.018 in to facilitate advancement of the catheter to and through the stenosis to be dilated. The product's catheter includes a tapered tip to facilitate advancement of the catheter to and through the stenosis. Two radiopaque marker bands (one proximal and one distal), in conjunction with fluoroscopy, enable accurate positioning of the balloon. The effective length of the balloon catheter is 200 cm; catheter markers indicate the exit of the dilatation catheter tip out of the guiding catheter (one at 90 cm and two at 100 cm).

5. Indications for Use

The Sterling Monorail PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal, renal, and

carotid arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

6. Comparison of Technological Characteristics with the Predicate Device

The Sterling Monorail PTA Balloon Dilatation Catheter has the same intended use/ indication for use, principle of operation, sterilization method, as the predicate Sterling MONORAIL PTA Balloon Dilatation Catheter (K162350).

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

- Longer catheter length of 200cm
- Increase in catheter outer diameter and sheath compatibility

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 to the predicate device.

7. Performance Data

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

Sterilization

Sterilization Testing

Bench Testing

- Dimensional Verification
- Simulated Use
- Balloon Inflation & Deflation Time
- Catheter Bond Strength
- Flexibility & Kink test
- Torque Strength
- Shaft & Bond Burst
- Catheter Extension & Deflation
- Packaging Testing
- Design Validation Testing

8. 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 Subject Device to the predicate Sterling MONORAIL PTA Balloon Dilatation Catheter (K162350).