March 24, 2022

Boston Scientific Corporation
Ms. Aoife O'Flaherty
Senior Regulatory Affairs Specialist
Ballybrit Business Park
Galway, Ireland

Re: K220629
Trade/Device Name: Emerge Monorail 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: March 3, 2022
Received: March 4, 2022

Dear Ms. O'Flaherty:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220629

Device Name
Emerge Monorail PTCA Dilatation Catheter

Indications for Use *(Describe)*
The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (1.20 mm balloon models) are indicated as pre-dilatation catheters in the stenotic portion of a coronary artery or bypass graft stenosis (≥70% stenosis).

The Emerge Over-The-Wire (balloon models 1.50-4.00 mm) and Emerge Monorail PTCA Dilatation Catheters (balloon models 1.50-5.00 mm) are indicated for the balloon catheter dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

The Emerge Over-The-Wire (balloon models 2.00-4.00 mm) and Emerge Monorail PTCA Dilatation Catheters (balloon models 2.00-5.00 mm) are also indicated for the postdelivery expansion of balloon expandable stents (bare metal and drug-eluting)

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
per 21 CFR §807.92

K220629

Sponsor	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA
Contact Name and Information	Aoife O'Flaherty Ballybrit Business Park, Galway, Ireland. Phone: 353-91-517299 Email: Aoife.OFlaherty@bsci.com
Date Prepared	March 3, 2022
Proprietary Name	Emerge™ Monorail™ PTCA Dilatation Catheter
Common Name	PTCA Dilatation Catheter
Product Code	LOX
Classification	Class II, 21 CFR Part 870.5100
Predicate Device	Emerge™ Monorail™ PTCA Dilatation Catheter, K163174, cleared December 14, 2016
Reference Device	Apex™ PTCA Dilatation Catheter, P860019/S208, approved November 7, 2008

Device Description

The Emerge™ Monorail™ (MR) PTCA Dilatation Catheter is a sterile, single-use, intravascular medical devices used to widen coronary artery blockages and/or dilate coronary artery stents upon stent placement. The catheter consists of a shaft with a Pebax balloon near the distal tip and is available in a range of balloon sizes.

Indications for Use / Intended Use

The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (1.20 mm balloon models) are indicated as pre-dilatation catheters in the stenotic portion of a coronary artery or bypass graft stenosis (≥70% stenosis).

The Emerge Over-The-Wire (balloon models 1.50-4.00 mm) and Emerge Monorail PTCA Dilatation Catheters (balloon models 1.50-5.00 mm) are indicated for the balloon catheter dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

The Emerge Over-The-Wire (balloon models 2.00-4.00 mm) and Emerge Monorail PTCA Dilatation Catheters (balloon models 2.00-5.00 mm) are also indicated for the post-delivery expansion of balloon expandable stents (bare metal and drug-eluting).

Comparison of Technological Characteristics

The proposed Emerge™ Monorail™ PTCA Dilatation Catheter sizes are substantially equivalent to the predicate Emerge™ Monorail™ PTCA Dilatation Catheter, cleared by FDA under premarket notification K163174, December 14, 2016. The proposed 4.50mm and 5.00mm diameter (for 8 – 20mm lengths) and 40mm length (for 2.00, 2.50, 3.00, 3.50, and 4.00mm diameter) Emerge™ Monorail™ balloon sizes serve as an extension to the cleared Emerge™ Monorail™ matrix of balloons 1.20 - 4.00mm in diameter and 8 - 30mm in length.

The proposed and predicate devices share the following technological characteristics:

- Fundamental device design and intended use
- Device materials
- Packaging materials and design
- Sterilization method
- Fundamental manufacturing processes

The proposed and predicate devices differ in the following technological characteristic:

- Balloon lengths and diameters

Non-clinical Performance Data

Bench testing was performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed Emerge MR device has been designed and tested to assure conformance to the requirements for its intended use.

The following performance tests were completed on the proposed Emerge MR devices:

- Effective Length
- Crossing Profile
- Balloon Preparation, Deployment and Retraction
- Withdrawal into a Guide Catheter
- Balloon Fatigue
- Balloon Inflation and Deflation
- Balloon Coating Integrity
- Particulate Evaluation

The following tests were leveraged from the predicate/reference devices:

- Shaft Inner and Outer Diameter
- Balloon Rated Burst Pressure
- Balloon Rated Burst Pressure (in Stent)
- Balloon Fatigue (select balloon sizes only)
- Balloon Fatigue (Repeat Balloon Inflations; in Stent)
- Balloon Compliance
- Catheter Bond Strength
- Tip Pull Test
- Flexibility and Kink Test
- Torque Strength
- Radiopacity
- Shaft Coating Integrity
- Shelf Life
- Biocompatibility
- Sterilization

Conclusion

Based on the indications for use, technological characteristics, and performance testing, the proposed Emerge™ Monorail™ PTCA Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to Emerge™ Monorail™ PTCA Dilatation Catheter (K161374).