May 25, 2023

Boston Scientific
Gabrielle Reynolds
Regulatory Affairs Specialist II
Two Scimed Place
Maple Grove, Minnesota 55311

Re: K231176
Trade/Device Name: Stingray LP Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 25, 2023
Received: April 25, 2023

Dear Gabrielle Reynolds:

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2023.05.25 15:21:58 -04'00'

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.

510(k) Number *(if known)*
K231176

Device Name
Stingray LP Catheter

Indications for Use *(Describe)*
The Stingray LP Catheter is indicated for directing, steering, controlling, and supporting a guidewire in order to access discrete regions of the coronary vasculature.

When used as part of the system consisting of the CrossBoss™ Catheter, Stingray LP Catheter, and Stingray Guidewire, the Stingray LP Catheter is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic coronary lesions (including chronic total occlusions [CTOs]) prior to PTCA or stent intervention.

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

Sponsor	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA
Contact Name and Information	Gabrielle Reynolds Two Scimed Place Maple Grove, Minnesota Email: gabrielle.reynolds@bsci.com
Date Prepared	April 25 , 2023
Proprietary Name	Stingray™ LP Catheter
Common Name	Percutaneous Catheter
Product Code	DQY
Classification	Class II, 21 CFR Part 870.1250
Predicate Device	Stingray™ LP Catheter, K152401, cleared December 4, 2015

Device Description

The Stingray LP Catheter facilitates the placement, support and steering of a guidewire into discrete regions of the coronary vasculature through the central guidewire lumen or through one of two side-ports. These side-ports are on opposite sides of the balloon and are identified by radiopaque markers. The side-ports communicate with the central guidewire lumen and facilitate guidewire steering (at an angle to the central lumen) by allowing the guidewire to exit the Stingray LP Catheter. The Stingray LP Catheter contains a small balloon used for fluoroscopic orientation on the distal tip of a flexible shaft. The distal end of the catheter is hydrophilic coated. The Stingray LP Catheter is compatible with 6F guide catheters with minimum inner diameter of 0.070 in (1.7 mm), and may be used with guidewires ≤0.014 in (0.36 mm).

Indications for Use / Intended Use

The Stingray LP Catheter is indicated for directing, steering, controlling, and supporting a guidewire in order to access discrete regions of the coronary vasculature.

When used as part of the system consisting of the CrossBoss™ Catheter, Stingray LP Catheter, and Stingray Guidewire, the Stingray LP Catheter is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic coronary lesions (including chronic total occlusions [CTOs]) prior to PTCA or stent intervention.

Comparison of Technological Characteristics

The proposed Stingray LP Catheter incorporates substantially equivalent materials, packaging, operating principles, fundamental scientific technology, manufacturing processes, sterilization process, and intended use as the predicate Stingray LP Catheter (K152401).

Non-clinical Performance Data

Bench and Biocompatibility testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed Stingray LP Catheter has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the device testing.

The following bench tests were completed in support of the proposed Stingray LP Catheter:

- Balloon Preparation, Deployment and Retraction
- Balloon Rated Burst Pressure (RBP)
- Catheter Bond Strength
- Flexibility and Kink Test
- Torque Strength Test

The following biocompatibility tests were completed in support of the proposed Stingray LP Catheter:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Materials Mediated Pyrogenicity
- Hemolysis (Direct Contact)
- Hemolysis (Extract Method)
- Partial Thromboplastin Time
- Platelet and Leukocyte Count
- Complement Activation
- USP <661> Physiochemical
- Genotoxicity

Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the proposed Stingray™ LP Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the predicate Stingray™ LP Catheter (K152401).