September 6, 2022

Boston Scientific Corporation
Heather Schuchard
Senior Regulatory Affairs Specialist
One Scimed Place
Maple Grove, Minnesota 55311

Re: K220962
Trade/Device Name: ROTAPRO Rotational Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: Class II
Product Code: MCW
Dated: March 31, 2022
Received: April 1, 2022

Dear Heather Schuchard:

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)*
K220962

Device Name
ROTAPRO Rotational Atherectomy System

Indications for Use *(Describe)*
The Peripheral ROTAPRO is intended for percutaneous use in the peripheral vessels in patients with occlusive atherosclerotic disease who are acceptable candidates for endovascular procedures.

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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510(k) Summary
Per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Heather Schuchard Senior Regulatory Affairs Specialist Phone: 763.494.1706 Fax: 763.494.2981 e-mail: Heather.Schuchard@bsci.com
Date Prepared	31 March 2022
Proprietary Name	Peripheral ROTAPRO™ Rotational Atherectomy System
Common Name	Rotational Atherectomy System
Product Code	MCW – Catheter, Peripheral, Atherectomy
Classification	Class II, 21 CFR Part 870.4875 – Intraluminal Artery Stripper
Predicate Device	K133566 -- Rotablator™ Rotational Atherectomy System with Peripheral RotaLink Plus™
Reference Devices	P900056 ROTAPRO Rotational Atherectomy System
Device Description	The Peripheral ROTAPRO Rotational Atherectomy System consists of an Advancer pre-connected to a Catheter. The advancer functions as a guide for the sliding elements that control burr advancement and the catheter portion of the device guides the burr through the vasculature to the treatment site. The Peripheral ROTAPRO devices are provided sterile and non-pyrogenic unless the package has been opened or damaged. It is intended for one procedure use only.
Intended Use of Device	The Peripheral ROTAPRO is intended to ablate occlusive material and restore luminal patency in the peripheral vasculature.
Indications for Use	The Peripheral ROTAPRO is intended for percutaneous use in peripheral vessels in patients with occlusive atherosclerotic disease who are acceptable candidates for endovascular procedures.
Comparison of Technological Characteristics	The Peripheral ROTAPRO Rotational Atherectomy System is substantially equivalent to the Rotablator Rotational Atherectomy System (predicate device) and identical to the IC ROTAPRO Rotational Atherectomy System (reference device).

Characteristic	**Peripheral ROTAPRO™ Rotational Atherectomy System (Subject)**	**Rotablator™ Rotational Atherectomy System with Peripheral RotaLink Plus™ (Predicate)**	**Interventional Cardiology ROTAPRO (Reference Device)**
Product Code	MCW	MCW	N/A-Interventional Cardiology ROTAPRO product code is for cardiovascular device
Class	II	II	III
Device Regulation	21 CFR Part 870.4875 – Intraluminal Artery Stripper	21 CFR Part 870.4875 – Intraluminal Artery Stripper	N/A-Device regulation not applicable for Class III devices.

Indications for Use	The Peripheral ROTAPRO is intended for percutaneous use in peripheral vessels in patients with occlusive atherosclerotic disease who are acceptable candidates for endovascular procedures.	The Rotablator Rotational Atherectomy System is intended for percutaneous use in the peripheral vessels in patients with occlusive atherosclerotic disease who are acceptable candidates for endovascular procedures.	Percutaneous rotational coronary atherectomy with the ROTAPRO Rotational Atherectomy System, as a sole therapy or with adjunctive percutaneous coronary intervention (PCI) is indicated in patients with calcific coronary artery disease who meet one of the following selection criteria: •Singlevesselatherosclerоticcoronaryarterydiseasewithastenosisthatcanbepassed with a guidewire; •Multiplevesselcoronaryarterydiseasethatinthephysician'sjudgmentdoesnotpose undue risk to the patient; •Patients who have had prior PCI, and who have native coronary artery post-balloon angioplasty restenosis; or, •Native vessel atherosclerotic coronary artery disease that is less than 25 mm in length.
Mechanism of Operation	The ROTAPRO Console delivers pneumatic output to the Advancer gas turbine, enabling rotation of the burr. The Console provides controls for and monitors the rotational speed of the burr and displays the operator and procedural information. The diamond boated burr ablates plaque and calcium into fine particles that are disposed of by the body's reticuloendothelial system while leaving healthy tissue unharmed.	Same	Same
Single Use Catheter/Burr	Yes	Yes	Yes
Catheter Length/Catheter Sheath OD	135 cm/1.4mm	Same	Same
Rotational Profile	Brass/Diamonds	Same	Same

	Rotation Cutting		
Burr Rotation Mechanism	Pneumatically activated turbine	Same	Same
Advancer/Catheter/ Burr Sterilization Method	EO	Same	Same
Mode Selection and Burr Control	Advancer Button	Foot Petal	Advancer Button
Console Control	Software Logic	Analog Circuit Logic	Software Logic
Console Design	LED Display with Sleek Housing	Display with Metal Housing	LED Display with Sleek Housing
Advancer Electrical/Gas Line Connection	Streamlined Gas/Electrical Harness	No Electrical Gas Line	Streamlined Gas/Electrical Harness
New Accessories	ROTAGO Cart and IV Stand	None	ROTAPRO Cart and IV Stand

Performance Data

To demonstrate substantial equivalence and adherence to applicable standards and guidance the following bench testing was performed:

- Anatomically Relevant Simulated Use (Functional Life, System Speed, Steady State Stall Torque, Dynamic Stall Torque, and Transient Response)
- EMC Testing: EN 60601-1-2

All other testing was leveraged from the FDA approved reference device.

The patient contacting (direct and indirect) materials of the proposed Peripheral ROTAPRO device are identical to the currently marketed IC ROTAPRO device (P900056/S166) and predicate Peripheral Rotablator Advancer (K133566) in formulation, processing, sterilization, and geometry. No other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

Conclusion

Based on the indications for use, technological characteristics, safety and performance testing, the Peripheral ROTAPRO Rotational Atherectomy System has shown to be appropriate for its intended use and is considered to be substantially equivalent to the Rotablator Rotational Atherectomy System with Peripheral RotaLink Plus (K133566).