September 14, 2021

C.R. Bard, Inc.
Aaron Conovaloff
Regulatory Affairs Manager
1625 West 3rd St
Tempe, Arizona 85281

Re: K211738
Trade/Device Name: Rotarex™ Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW, DQX
Dated: August 17, 2021
Received: August 18, 2021

Dear Aaron Conovaloff:

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)*
K211738

Device Name
Rotarex™ Atherectomy System

Indications for Use *(Describe)*
The Rotarex™ Atherectomy System is intended for use as an atherectomy device and to break up and remove thrombus from native peripheral arteries or peripheral arteries fitted with stents, stent grafts or native or artificial bypasses.

Contraindications:
- In patients not suitable for atherectomy/thrombectomy
- In the cardiopulmonary, coronary, carotid, cerebral and renal vasculature
- In vessels that are undersized for the particular device used
- In the venous 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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Rotarex™ Atherectomy System

510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc 1625 West 3rd Street Tempe, Arizona 85281
Phone:	602-830-5453
Fax:	321-949-0436
Contact:	Aaron Conovaloff, Regulatory Affairs Manager
Date	June 4, 2021

Subject Device Name:

Device Trade Name:	**Rotarex™ Atherectomy System**
Common or Usual Name:	Intraluminal artery stripper
Product Code:	MCW, DQX
Classification:	Class II
Review Panel:	Cardiovascular
Regulation Number:	21 CFR 870.4875

Predicate Device:

- Straub Endovascular System (K172315; cleared April 12, 2018)

Reference Device:

- B-Laser Atherectomy System (K181642; cleared October 5, 2018)

Device Description:

The Rotarex™ Atherectomy System is made up of a single use Rotarex™ Atherectomy Catheter Set and the Drive System, consisting of the control unit, motor and foot switch. For more detail on the Drive System, please see the manual provided with the Drive System. Read and understand all instructions prior to attempting any atherectomy procedure with the Rotarex™ Atherectomy System or any of its components.

The Rotarex™ Atherectomy Catheter Set is composed of multiple components, including the Rotarex™ Atherectomy Catheter, guidewire, collecting bag, and sterile drape. Rotarex™ Atherectomy Catheters are over-the-wire, single use, percutaneous devices for the removal of

atheromatic plaque and thrombi in native arteries or arteries fitted with stents, stent grafts or native or artificial bypasses. The catheters are latex and phthalate free, and consist of a flexible outer covering, a rotating head, and a rotating helix which runs the length of the catheter. A lumen for the passage of the supplied guidewire runs the entire length of the helix and through the head of the catheter.

The catheter head is made up of two overlying metal cylinders, with two side openings. The outer cylinder is connected to the rotating helix, and the inner cylinder to the catheter shaft. The helix and the catheter head rotate at approximately 40,000-60,000 rpm depending on the model, by means of a gear box in the catheter housing and a motor contained within the catheter handle driven by the Drive System. The rotating outer cylinder is fitted with abrading facets at its foremost tip.

The Rotarex™ Atherectomy System Guidewires are 0.018" and are included with each Rotarex™ Atherectomy Catheter Set. These guidewires consist of a Nitinol core and a PTFE coating with a 9.5cm hydrophilic distal coating and a 4 cm angled flex tip.

All components within the Rotarex™ Atherectomy Catheter Sets are supplied sterile for single use only. The method of sterilization is ethylene oxide.

Catheter Size	Minimum Vessel Diameter	Catheter External Diameter	Nominal Rotation (RPM)	Maximum Aspiration (ml/min)	Guidewire Size & Length
6F 110 cm	3 mm	2.0 mm	60,000	45	0.018" 270 cm
6F 135 cm	3 mm	2.0 mm	60,000	45	0.018" 320 cm
8F 85 cm	5 mm	2.7 mm	40,000	75	0.018" 220 cm
8F 110 cm	5 mm	2.7 mm	40,000	75	0.018" 270 cm

Indications for Use of Device:

The Rotarex™ Atherectomy System is intended for use as an atherectomy device and to break up and remove thrombus from native peripheral arteries or peripheral arteries fitted with stents, stent grafts or native or artificial bypasses.

Contraindications:

- In patients not suitable for atherectomy/thrombectomy
- In the cardiopulmonary, coronary, carotid, cerebral and renal vasculature
- In vessels that are undersized for the particular device used
- In the venous vasculature

Comparison to Predicate Devices:

The subject Rotarex™ Atherectomy System has the following similarities to the predicate Rotarex® S catheter (a component of the Straub Endovascular System; K172315, cleared April 12, 2018):

- Intended use
- Target population/conditions of use (anatomical location of use, how device interacts with

other devices, interaction with patient)
- Principles of operation/mechanism of action
- Fundamental scientific technology
- Sterilization method
- Sterility assurance level

The subject Rotarex™ Atherectomy System has the following similarities to the reference B-Laser Atherectomy System (K181642, cleared October 5, 2018):
- Intended use
- Indications for use
- Target population/conditions of use (anatomical location of use, how device interacts with other devices, interaction with patient)
- Sterilization method

The subject Rotarex™ Atherectomy System incorporates the design of the Rotarex® S catheter predicate with the in-stent restenosis indication of the reference B-Laser Atherectomy System device. Note that the design, materials, and methods of manufacture of the subject device and the Rotarex® S catheter predicate are identical; the only differences are the expansion of the indications for use to include use in peripheral arteries fitted with stents or stent grafts and in native or artificial bypasses, and to remove several of the contraindications in the IFU.

The removed contraindications are not critical to the intended use of this device. Some of these contraindications are being removed completely, either in light of data to support their removal or because the corresponding risk information is already communicated in other areas of the IFU. Other contraindications are being restated as warnings, as warnings have been determined to be a more appropriate way to present the corresponding risk information. Because the corresponding risk information is still presented appropriately in the IFU, removal of these contraindications does not affect the safety and effectiveness of the device when used as labeled.

Performance Data:

To demonstrate substantial equivalence of the subject device to the predicate device, its technological characteristics and performance criteria were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Assessment procedures, the following *in vitro* tests were performed on the subject device:
- Simulated use of atherectomy device in a stent
- Heat generation
- Embolization analysis

Clinical Literature

A significant body of medical literature confirms the frequent usage of the Rotarex™ Atherectomy System for the treatment of ISR as well as for the debulking of occlusions in iliac arteries and bypass grafts. Literature was reviewed to examine the safety and efficacy of the Rotarex™ Atherectomy System compared to percutaneous transluminal angioplasty (PTA) when used for ISR treatment. In addition, the safety, technical success, and clinical outcome for iliac arteries was addressed by description of the results from all-comer Rotarex™ Atherectomy System studies. The debulking of bypass grafts using the Rotarex™ Atherectomy System was compared with thrombectomy devices, Ekos (Boston Scientific) and Indigo (Penumbra), and with open surgery. The results of the literature review were used to determine the acceptability of the benefit-risk profile of Rotarex™ Atherectomy Systems used for the treatment of ISR and debulking of occlusions in iliac-arteries and bypass-grafts.

Conclusions:

The results from both in vitro studies and clinical literature demonstrate that the technological characteristics and performance criteria of the subject Rotarex™ Atherectomy System are substantially equivalent to the predicate device, and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

The subject device, the Rotarex™ Atherectomy System, met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. Rotarex™ Atherectomy System is substantially equivalent to the legally marketed predicate device, the Rotarex® S catheter.