January 30, 2025

Bard Peripheral Vascular, Inc.
Aaron Conovaloff
Regulatory Affairs Manager
1625 W. 3rd Street
Tempe, Arizona 85281

Re: K242757
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: September 12, 2024
Received: January 21, 2025

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2025.01.30 16:48:52 -05'00'

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.

510(k) Number *(if known)*
K242757

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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	September 12, 2024

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:

- Rotarex™ Atherectomy System (K211738; cleared September 14, 2021)

Summary of Change:

No changes have been made to the subject Rotarex™ Atherectomy System. The purpose of the submission is to obtain FDA clearance related to proposed revisions to the existing Rotarex™ Atherectomy System instructions for use (IFU). These IFU updates are being made to further clarify and emphasize important details regarding the procedural steps that are intended to reduce the risk of Rotarex™ catheter breakage events (including helix breaks) with use of the Rotarex™ catheter by supplementing and consolidating relevant information into one location within the warning section. These clarifications emphasize the importance of the procedural steps and anatomical considerations. An additional diagram illustrating existing instructions for device use is provided. BD will continue to monitor the Rotarex™ Atherectomy System via post-market data sources and is committed to investigating whether additional factors may exist that could contribute to helix fracture and/or breakage events to determine what, if any, additional actions may be needed.

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.

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.

Technological Comparison to Predicate Device:

The technological characteristics of the subject device, the Rotarex™ Atherectomy System, are identical to those of the predicate device, in terms of the following:

- Identical Intended use
- Identical Indications for use
- Identical target population

- Identical delivery system design
- Identical filter design and material
- Identical fundamental scientific technology
- Identical packaging configuration
- Identical Sterility Assurance and method of Sterilization

Performance Data:

As no changes are being made to the Rotarex™ Atherectomy System associated with this 510(k) notice, no new performance testing was conducted on the subject device.

Conclusions:

The Rotarex™ Atherectomy System is substantially equivalent to the legally marketed predicate device. No changes have been made to the device or delivery system. The only changes being made are to revise the existing Rotarex™ Atherectomy System instructions for use (IFU). These IFU updates are being made to clarify the procedural steps that are intended to reduce the risk of Rotarex™ catheter breakage events (including helix breaks) with use of the Rotarex™ catheter. BD will continue to monitor the Rotarex™ Atherectomy System via post-market data sources and is committed to investigating whether additional factors may exist that could contribute to helix fracture and/or breakage events to determine what, if any, additional actions may be needed.