March 31, 2023

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

Re: K230356
Trade/Device Name: Aspirex™ Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW, DQX
Dated: February 9, 2023
Received: February 9, 2023

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 W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.03.31 14:49:03 -04'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230356

Device Name
Aspirex™ Thrombectomy System

Indications for Use *(Describe)*
The Aspirex™ Thrombectomy System is indicated for the removal of acute emboli and thrombi from vessels of the peripheral venous system.

The 6F and 8F Aspirex™ Thrombectomy Systems are indicated for the removal of acute emboli and thrombi from hemodialysis access grafts and native arteriovenous fistulas.

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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Aspirex™ Thrombectomy 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:	February 9, 2023

Subject Device Name:

Device Trade Name:	**Aspirex™ Thrombectomy System**
Common or Usual Name:	Embolectomy catheter
Product Code:	QEW, DQX
Classification:	Class II
Review Panel:	Cardiovascular
Regulation Number:	21 CFR 870.5150

Predicate Device:

- Aspirex™ Thrombectomy System (K220270; cleared June 21, 2022)

Reference Device:

- AngioJet Ultra AVX Thrombectomy Set (K133629; cleared February 14, 2014)

Device Description:

The Aspirex™ Thrombectomy System–composed of the Aspirex™ Thrombectomy Catheter Set and the Drive System–is designed for efficient thrombus removal with strong, continuous, and controlled aspiration. The Drive System is composed of the control unit, a motor, and a footswitch. The Drive System is small and portable, and designed for simple, quick set up and ease of use.

The Aspirex™ Thrombectomy Catheter Set is composed of multiple components, including the Aspirex™ Thrombectomy Catheter, the Aspirex™ Guidewire, collecting bag, and sterile drape. The Aspirex™ Thrombectomy Catheter consists of a braided shaft, to add strength and torque, through which runs a helix. The catheter shaft connects to a metallic head constructed with a

side window(s) at the distal end. The head has a smooth, rounded, atraumatic shape so unintentional contact with the vessel wall will not cause damage to the vessel. Contact with the vessel wall is not necessary for the catheter to exert its effect. An ergonomic handle, connected to the catheter shaft at the proximal end, connects to the motorized Drive System via a magnetic clutch. The entire catheter tracks over the Aspirex™ Guidewire previously navigated across the thrombus/embolus.

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
10F 110 cm	8 mm	3.3 mm	40,000	130	0.025" 270 cm

Indications for Use of Device:

The Aspirex™ Thrombectomy System is indicated for the removal of acute emboli and thrombi from vessels of the peripheral venous system.

The 6F and 8F Aspirex™ Thrombectomy Systems are indicated for the removal of acute emboli and thrombi from hemodialysis access grafts and native arteriovenous fistulas.

Contraindications:

- Not for use in vessels of the cardiac, pulmonary, coronary, and neurovasculature

Comparison to Predicate Devices:

The subject Aspirex™ Thrombectomy System has the following similarities to the predicate Aspirex™ Thrombectomy System (K220270; cleared June 21, 2022):

- Same intended use
- Similar target population/conditions of use (how device interacts with other devices, interaction with patient)
- Same method of sterilization
- Same operating principle
- Same fundamental scientific technology

- Same design and performance specifications, manufacturing methods, raw materials, formulation, processing, sterilization (including dose and duration), packaging, suppliers, proportional surface area of each patient contacting component, geometry, and chemical additives

The subject Aspirex™ Thrombectomy System has the following similarities to the reference AngioJet Ultra AVX Thrombectomy Set (K133629, cleared February 14, 2014):

- Similar operating principle (mechanical aspiration)
- Similar fundamental scientific technology (mechanical aspiration)
- Similar intended use
- Similar target population/conditions of use (how device interacts with other devices, interaction with patient)

The subject Aspirex™ Thrombectomy System is identical in manufacturing and design to the predicate Aspirex™ Thrombectomy System, and adds an indication for arteriovenous use, which is similar to that of the reference AngioJet Ultra AVX Thrombectomy Set.

Performance Data:

A review of clinical data from scientific literature and clinical study reports, focusing on device performance and clinical outcomes of percutaneous mechanical thrombectomy with the Aspirex™ Thrombectomy System for the removal of occlusions from hemodialysis access grafts and native arteriovenous fistulas, was performed.

Primary patency rates were analyzed as clinical benefits, and it could be concluded that vascular access (in both hemodialysis access grafts and native arteriovenous fistulas) patency rates after treatment with the Aspirex™ device are similar to that observed with treatment with other mechanical thrombectomy devices or surgery. Sub-group analyses of solely hemodialysis access grafts or native arteriovenous fistulas were also carried out and confirmed the results of the pooled analysis.

As demonstrated by the systematic analysis of the scientific literature and clinical study reports, it can be concluded that use of the Aspirex™ Thrombectomy System in thrombectomy in hemodialysis access grafts and native arteriovenous fistulas does not raise new questions of safety and effectiveness; the device provides satisfactory clinical outcomes in terms of patency rates and the functioning of hemodialysis vascular access.

Conclusions:

The subject and predicate devices are identical with respect to manufacturing and design. The only difference between the subject and predicate devices is an expanded indications for use statement to include use in hemodialysis access grafts and native arteriovenous fistulas. The clinical data obtained for the Aspirex™ Thrombectomy System demonstrated that there are no new questions of safety and effectiveness raised by the expanded indications for use. Therefore, the Aspirex™ Thrombectomy System is substantially equivalent to the legally marketed predicate device, the Aspirex™ Thrombectomy System.