June 21, 2022

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

Re: K220270
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: May 19, 2022
Received: May 20, 2022

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)*
K220270

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.

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	January 28, 2022

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:

- Indigo Aspiration System (K192833; cleared December 20, 2019)

Reference Device:

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

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.

The Aspirex™ Guidewire has a LubriSkin PTFE-coated nitinol core wire with a gold-plated tungsten tip coated with DSM ComfortCoat® hydrophilic coating. The guidewire is used to initially cross through the area to be treated.

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.

Contraindications:

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

Comparison to Predicate and Reference Devices:

The subject Aspirex™ Thrombectomy System has the following similarities to the predicate Indigo Aspiration System (K192833; cleared December 20, 2019):

- Intended use
- Target population/conditions of use (anatomical location of use, how device interacts with other devices, interaction with patient)
- Sterilization method

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

- Intended use
- Indications for use
- Principles of operation/mechanism of action
- Fundamental scientific technology
- Target population/conditions of use (how device interacts with other devices, interaction with patient)
- Sterilization method
- Sterility assurance level

The subject Aspirex™ Thrombectomy System incorporates many of the design characteristics of the reference Rotarex® S catheter with the indication for use of the predicate Indigo Aspiration System.

Attribute	Subject Device – Aspirex™ Thrombectomy Catheter	Predicate Device – Indigo Aspiration System (K192833)	Reference Device – Rotarex® S Catheter (K172315)	Rationale
Manufacturer	Straub Medical AG	Penumbra, Inc.	Straub Medical AG	Identical to Rotarex® S
Product Code	QEW/DQX	QEW/DXE	MCW/QEW/DQX	Combination of predicate and reference devices.
Intended Use	Thrombectomy	Thrombectomy	Atherectomy and thrombus removal	Identical to Indigo, and included in Rotarex® S use
Indications for Use	The Aspirex™ Thrombectomy System is indicated for the removal of acute emboli and thrombi from vessels of the peripheral venous system.	As part of the Indigo Aspiration System, the Indigo Aspiration Catheters and Separators are indicated for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and for the treatment of pulmonary embolism.	When operated with a Rotarex™ S single use catheter, the Straub Endovascular System is intended for use as an atherectomy device and to break up and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, pulmonary, iliac or renal vasculature.	Similar to Indigo, but the language has been clarified in the subject indications to be more clinically relevant. Subject indications also do not include treatment of pulmonary embolism or arterial vessels.

Contraindications	• Not for use in vessels of the cardiac, pulmonary, coronary, or neurovasculature	• Not for use in the coronaries or the neurovasculature.	• In the cardiopulmonary, coronary, cerebral, iliac and renal vasculature • In the venous vasculature • In instances of persistent vasospasm • In patients not suitable for atherectomy/ thrombectomy • In patients with known or suspected allergies to any component of the Straub Endovascular System • In patients with haemodynamic instability, shock or severe coagulatory disorders • In patients where it is impossible to achieve sufficient anticoagulation and platelet aggregation inhibition • In areas of known or suspected infection, especially at the puncture site or target vessel segment • In vessels which are oversized or undersized for the particular Rotarex® S catheter used • In stents, stent grafts or bypass grafts	Similar to Indigo, but use in cardiac and pulmonary vessels is also contraindicated, as the subject device is not indicated for treatment of pulmonary embolism. Subject has different contraindications from Rotarex® S, but please note that the vast majority of the contraindications listed for the reference device were removed under K211738.

			• Without the use of a Straub provided guidewire • When the Straub provided guidewire cannot completely cross the target lesion • Where the Straub provided guidewire is in a subintimal position of any length • Where the Straub provided guidewire has become threaded or entangled in the wire mesh of a stent, stent graft or the lining of a stent graft • Where the target lesion is located in a region of marked vessel tortuosity (has a radius of curvature ≤2 cm) or is heavily calcified • Where pre-existing damage is present in the vessel wall at or near the target lesion from prior surgery, aneurysms or other disease • During MRI procedures or where electrical current may be passed to an undesired location via the catheter, e.g., during electrocautery, electrosurgery or	

Attribute	Subject Device – Aspirex™ Thrombectomy Catheter	Predicate Device – Indigo Aspiration System (K192833)	Reference Device – Rotarex® S Catheter (K172315)	Rationale
			defibrillation. The Rotarex® S catheter and guidewire must be entirely removed before these therapies are administered, even in an emergency situation • Where the recommended separation distances from Radio Frequency and Electro-Magnetic Interference (EMI) sources cannot be maintained (Reference the manual for the Drive System) • Where any component of the Straub Rotarex® S Endovascular System has sustained damage, including any breech of the sterile barrier	
System Components	Catheter, console/control unit, guidewire, collecting bag, sterile drape for motor	Catheter, aspiration pump and canister, aspiration tubing, separator	Catheter, console/control unit, guidewire, collecting bag, sterile drape for motor	Identical to Rotarex® S
Catheter Diameter	6F, 8F, 10F	3F, 5F, 5.3F, 6F, 8F	6F, 8F	6F and 8F sizes identical to both predicate and reference devices. CAT12 model of Indigo predicate (K192981) is compatible with 12F sheath, so 10F subject device is within that range.
Catheter Length	85, 110, 135 cm	50, 85, 115, 132, 135, 140, 150 cm	85, 110, 135 cm	Identical to Rotarex® S, within same range as Indigo.

Attribute	Subject Device – Aspirex™ Thrombectomy Catheter	Predicate Device – Indigo Aspiration System (K192833)	Reference Device – Rotarex® S Catheter (K172315)	Rationale
Guidewire Compatibility	0.018", 0.025"	0.014"-0.038"	0.018"	Identical to Rotarex® S, addition of 10F size for 0.025" wire, within same range as Indigo.
Catheter Tip	Smooth, rounded stationary head	Torq, XTorq, Straight	Rotating atraumatic beveled head	Similar to Rotarex® S, but less potential for vessel trauma due to stationary head.
Aspiration	Active (Drive System)	Active (Aspiration Pump)	Active (Drive System)	Identical to Rotarex® S
Mechanism of Action	Aspiration	Aspiration	Front cutting/rotational	Identical to Indigo
Materials	All materials that come in contact directly or indirectly with body tissue or blood meet the guidelines in ISO 10993-1.	Biocompatible, commonly used for interventional devices	All materials that come in contact directly or indirectly with body tissue or blood meet the guidelines in ISO 10993-1.	Identical to Rotarex® S
Shelf Life	3 years	3 years	3 years	Identical to predicate and reference
Sterilization Method	EO	EO	EO	Identical to predicate and reference
Rotation Speed	40k, 60k RPM	N/A	40k, 60k RPM	Identical to Rotarex® S
Aspiration Rate	45, 75, 130 ml/min	42, 168, 270, 480 ml/min	45, 75 ml/min	Identical to Rotarex, but with 130 ml/min rate for 10F size, which is within range of Indigo rates.
Corrosion Resistance	When tested in accordance with the method in EN ISO 10555-1 annex A, metallic components of the catheter shall show no signs of corrosion.	Unknown	When tested in accordance with the method in EN ISO 10555-1 annex A, metallic components of the catheter shall show no signs of corrosion.	Identical to Rotarex® S

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:

- Catheter
  - Dimensional verification
  - Simulated use
  - Kink resistance
  - Heat generation
  - Aspiration rate
  - Debris removal and collection
  - Embolization analysis
  - Fatigue
  - Particulate evaluation
  - Trackability
  - Torsional strength
  - Biocompatibility
    - Acute systemic toxicity
    - Cell cytotoxicity
    - Complement activation
    - Direct hemolysis
    - Extractables characterization
    - Guinea pig maximization
    - Intracutaneous reactivity
    - Material mediated pyrogenicity
    - Partial thromboplastin time
    - Platelet and leukocyte count
- Guidewire
  - Surface
  - Corrosion
  - Fracture
  - Bending
  - Tensile strength
  - Overall length
  - Coil length
  - Max tip diameter
  - Guidewire body diameter
  - Tip flexibility
  - Coating integrity assessment
  - Particulate evaluation
  - Kink resistance
  - Lubricity

<u>Animal Study</u>
A GLP animal study was conducted to assess the safety and performance of the Aspirex™ catheter (test article) of the Aspirex Thrombectomy System in healthy veins, using the Indigo Aspiration Catheter (control article) of the Penumbra Indigo Aspiration System as a comparator. The secondary objective of this study was to assess the usability and performance of the other parts of the Aspirex™ Thrombectomy System in association with the Aspirex™ catheter: Straub Medical Drive System, guidewire, collection bag and sterile drape.

No evidence of stenosis or occlusion was observed in the vessels of any of the study animals at any fluoroscopy (with contrast) assessment. No evidence of intimal irregularities, vessel dissection, perforation, rupture, or other evidence of vessel injury was observed in the vessels of

any of the study animals at any fluoroscopy (with contrast) assessment or upon macroscopic assessment of the external aspect of the treated vessels. Microscopic findings in the treated vessels correlated with angiographic and macroscopic observations. Microscopic changes were of similar incidence and severity in both test and control groups and were limited to the intima (i.e. multifocal endothelial hypertrophy and intimal thickening due to fibrosis) in the treated vessels, with no vessel perforation, vessel dissection, rupture nor parietal hematoma, no medial injury (with the exception of degenerative changes in one acute control study animal) and no relevant inflammation of the vessel wall or surrounding tissues.

When comparing the results of clinical, biological and tissular response to the application of the Aspirex™ catheter and Indigo Aspiration Catheter, local and systemic tolerance appears equivalent in both groups. The usability and performance of the Aspirex™ catheter and Indigo Aspiration Catheter presented with similar results, with no adverse events.

Conclusions:

The results from both in vitro studies and a GLP animal study demonstrate that the technological characteristics and performance criteria of the subject Aspirex™ Thrombectomy 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 Aspirex™ Thrombectomy System, met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Aspirex™ Thrombectomy System is substantially equivalent to the legally marketed predicate device, the Indigo Aspiration System.