



December 6, 2024

Bard Peripheral Vascular, Inc
Gabrielle Wipper
Regulatory Affairs Specialist
1625 W 3rd St
Tempe, Arizona 85281

Re: K241946

Trade/Device Name: PeritX™ 1L Drainage Kit (90-1010); PeritX™ 2L Drainage Kit (90-2010); PeritX™ Peritoneal Catheter Kit (50-9000C); PeritX™ Peritoneal Catheter and Starter Kit (50-9900C); PeritX™ Peritoneal Catheter Mini Kit (50-9050A); PleurX™ Low Profile Catheter Mini Kit (50-8050); Valve Cap (50-7235A); PeritX™ Valve Kit (50-7272); Catheter Access Kit (50-7280A); Lockable Drainage Line (50-7245A); Lockable Drainage Line Kit (50-7265A); PleurX™ Supplemental Insertion Kit (50-7262); Procedure Pack (50-7290A); PleurX™ Vacuum Bottle, 500 mL (50-7205B); PleurX™ Vacuum Bottle, 1000 mL (50-7210); PleurX™ Drainage Kit, 500 mL (50-7500B); PleurX™ Drainage Kit, 1000 mL (50-7510); PleurX™ Patient Starter Kit, 1000 mL (50-0071); PeritX™ Drainage Bag, 2000 mL (50-9210); PeritX™ Drainage Kit, 2000 mL (50-9510)

Regulation Number: 21 CFR 876.5630

Regulation Name: Peritoneal Dialysis System And Accessories

Regulatory Class: Class II

Product Code: PNG

Dated: December 6, 2024

Received: December 6, 2024

Dear Gabrielle Wipper:

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,


Maura Rooney -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K241946

Device Name

PeritX™ 1L Drainage Kit (90-1010);
PeritX™ 2L Drainage Kit (90-2010);
PeritX™ Peritoneal Catheter Kit (50-9000C);
PeritX™ Peritoneal Catheter and Starter Kit (50-9900C);
PeritX™ Peritoneal Catheter Mini Kit (50-9050A);
PleurX™ Low Profile Catheter Mini Kit (50-8050);
Valve Cap (50-7235A);
PeritX™ Valve Kit (50-7272);
Catheter Access Kit (50-7280A);
Lockable Drainage Line (50-7245A);
Lockable Drainage Line Kit (50-7265A);
PleurX™ Supplemental Insertion Kit (50-7262);
Procedure Pack (50-7290A);
PleurX™ Vacuum Bottle, 500 mL (50-7205B);
PleurX™ Vacuum Bottle, 1000 mL (50-7210);
PleurX™ Drainage Kit, 500 mL (50-7500B);
PleurX™ Drainage Kit, 1000 mL (50-7510);
PleurX™ Patient Starter Kit, 1000 mL (50-0071);
PeritX™ Drainage Bag, 2000 mL (50-9210);
PeritX™ Drainage Kit, 2000 mL (50-9510)

Indications for Use (Describe)

The PeritX™ Drainage Kits are indicated for use only with the PeritX™ Peritoneal Catheter for intermittent drainage.

The PeritX™ Peritoneal Catheter System is indicated for intermittent, long-term drainage of symptomatic, recurrent, malignant and nonmalignant ascites that does not respond to medical management of the underlying disease and for the palliation of symptoms relate to recurrent ascites. The use of the PeritX™ Peritoneal Catheter for non-malignant ascites is limited to patients who are intolerant or resistant to maximum medical therapy, refractory to large volume paracentesis (LVP) and are not candidates for a trans-jugular intra hepatic portosystemic shunt or LVP. The PeritX™ Peritoneal Catheter is indicated for adults only.

The Lockable Drainage Line is used to drain fluid using standard wall suction, water seal drainage system, vacuum bottle, or other appropriate method.

For Pleural Use: The PleurX™ LP Catheter Mini Kit is indicated for intermittent, long-term drainage of symptomatic, recurrent, pleural effusion, including malignant pleural effusion and other recurrent effusions that do not respond to medical management of the underlying disease. The devices are indicated for the palliation of dyspnea due to pleural effusion and providing pleurodesis (resolution of the pleural effusion). The PleurX™ Low Profile Catheter is indicated for adults only.

For Peritoneal Use: The PleurX™ LP Catheter Mini Kit is indicated for intermittent, long term drainage of symptomatic, recurrent, malignant and non-malignant ascites that does not respond to medical management of the underlying disease and for the palliation of symptoms related to recurrent ascites. The use of the PleurX™ Low Profile Catheter for non-malignant ascites is limited

to patients who are intolerant or resistant to maximum medical therapy, refractory to large volume paracentesis (LVP) and are not candidates for a trans-jugular intrahepatic portosystemic shunt or LVP. The PleurX™ Low Profile Catheter is indicated for adults only.

The Lockable Drainage Line is used to drain fluid using standard wall suction, water seal drainage system, vacuum bottle, or other appropriate method.

The PeritX™ Valve Kit is indicated for use in adults only. The PeritX™ Valve Kit is designed for health care facility use only. There is no change to the PeritX™ Valve Kit within this submission.

For Pleural Use: The Catheter Access Kit is intended to provide access to the PleurX™ Catheter to inject and withdraw fluids.

For Peritoneal Use: The Catheter Access Kit is intended to provide access to the PeritX™ Catheter for aspiration and catheter maintenance.

The Lockable Drainage Line is indicated for use only with the PleurX™ Pleural Catheter and PeritX™ Peritoneal Catheter for intermittent drainage.

The Lockable Drainage Line Kit is indicated for use only with the PleurX™ Catheter and PeritX™ Catheter for intermittent drainage. The Lockable Drainage Line Kit is used to drain fluid using standard wall suction, water seal drainage system, glass vacuum bottle, or other appropriate method (portable suction).

The PleurX™ Supplemental Insertion Kit intended to aid in the percutaneous insertion of a PleurX™ Catheter into the pleural space and PeritX™ Catheter into the peritoneal space.

The Procedure Pack is indicated for dressing of the PleurX™ Pleural Catheter and PeritX™ Peritoneal Catheter and exit site.

The PleurX™ Drainage Kits are indicated for use only with the PleurX™ Catheter and PeritX™ Catheter for intermittent drainage.

The PeritX™ Drainage Bag is indicated for use only with the PeritX™ Peritoneal Catheter for intermittent drainage.

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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510(k) Summary (21 CFR 878.4300)

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 summary of the information upon which substantial equivalence determination is based is as follows:

1. Submitter Information:

Applicant: Bard Peripheral Vascular, Inc.
1625 West 3rd Street
Tempe, Arizona 85281, USA

Phone: 602-830-5063

Email: Gabrielle.Wipper@bd.com

Contact: Gabrielle Wipper, Regulatory Affairs Specialist

Date: August 29, 2024

2. Subject Device:

Device Trade Name: PeritX™ Peritoneal Catheter System

Common Name: Peritoneal Catheter System

Classification Name: Peritoneal, Drainage Catheter For Refractory Ascites, Long-Term Indwelling (Product Code: PNG)

Product Classification: II

Review Panel: Gastroenterology/Urology

Regulation Number/Name: 21 CFR 876.5630/Peritoneal dialysis system and accessories

3. Predicate Device:

PeritX™ Peritoneal Catheter System (K201155; Clearance Date October 21, 2020)

4. Device Description

The subject device, the PeritX™ Peritoneal Catheter System, includes the PeritX™ Peritoneal Catheter and PleurX™ Low Profile Catheter, sterile, single use indwelling peritoneal catheters, the PeritX™ Valve Kit, Catheter Access Kit, Lockable Drainage Line, Lockable Drainage Line Kit, PleurX™ Supplemental Insertion Kit, Procedure Pack, PleurX™ Drainage Kits, and the PeritX™ Drainage Bag that allow for the management of ascites at home.

The PeritX™ Drainage Kit (for vacuum-initiated drainage) is a sterile, single use fluid collection device used with the PeritX™ Peritoneal Catheter to drain fluid from the peritoneal cavity to relieve symptoms associated with malignant and non-malignant ascites. The PeritX™ Drainage Kit includes the PeritX™ Drainage Bag and Procedure Pack. The PeritX™ Drainage Kit is offered in two sizes (1L and 2L).

5. Indications for Use

The PeritX™ Peritoneal Catheter System is indicated for intermittent, long-term drainage of symptomatic, recurrent, malignant and nonmalignant ascites that does not respond to medical management of the underlying disease and for the palliation of symptoms related to recurrent ascites. The use of the PeritX™ Peritoneal Catheter for non-malignant ascites is limited to patients who are intolerant or resistant to maximum medical therapy, refractory to large volume paracentesis (LVP) and are not candidates for a trans-jugular intra hepatic portosystemic shunt or LVP. The PeritX™ Peritoneal Catheter is indicated for adults only.

The Lockable Drainage Line is used to drain fluid using standard wall suction, water seal drainage system, vacuum bottle, or other appropriate method.

For Pleural Use: The PleurX™ LP Catheter Mini Kit is indicated for intermittent, long-term drainage of symptomatic, recurrent, pleural effusion, including malignant pleural effusion and other recurrent effusions that do not respond to medical management of the underlying disease. The devices are indicated for the palliation of dyspnea due to pleural effusion and providing pleurodesis (resolution of the pleural effusion). The PleurX™ Low Profile Catheter is indicated for adults only.

For Peritoneal Use: The PleurX™ LP Catheter Mini Kit is indicated for intermittent, long term drainage of symptomatic, recurrent, malignant and non-malignant ascites that does not respond to medical management of the underlying disease and for the palliation of symptoms related to recurrent ascites. The use of the PleurX™ Low Profile Catheter for non-malignant ascites is limited to patients who are intolerant or resistant to maximum medical therapy, refractory to large volume paracentesis (LVP) and are not candidates for a trans-jugular intrahepatic portosystemic shunt or LVP. The PleurX™ Low Profile Catheter is indicated for adults only.

The Lockable Drainage Line is used to drain fluid using standard wall suction, water seal drainage system, vacuum bottle, or other appropriate method.

The PeritX™ Valve Kit is indicated for use in adults only. The PeritX™ Valve Kit is designed for health care facility use only. There is no change to the PeritX™ Valve Kit within this submission.

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The Lockable Drainage Line is indicated for use only with the PleurX™ Pleural Catheter and PeritX™ Peritoneal Catheter for intermittent drainage.

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The PleurX™ Supplemental Insertion Kit is intended to aid in the percutaneous insertion of a PleurX™ Catheter into the pleural space and PeritX™ Catheter into the peritoneal space.

The Procedure Pack is indicated for dressing of the PleurX™ Pleural Catheter and PeritX™ Peritoneal Catheter and exit site.

The PleurX™ Drainage Kits are indicated for use only with the PleurX™ Catheter and PeritX™ Catheter for intermittent drainage.

The PeritX™ Drainage Bag is indicated for use only with the PeritX™ Peritoneal Catheter for intermittent drainage. The PeritX™ Drainage Kits are indicated for use only with the PeritX™ Peritoneal Catheter for intermittent drainage.

6. Technological Comparison to Predicate Device

The technological characteristics of the subject device are substantially equivalent to those of the predicate device, in terms of following:

- Intended Use
- Patient Population
- Catheter-to-Accessory Interface
- Catheter Materials
- Catheter Design

- Mechanism of Action
- Fundamental Scientific Technology
- Patient Contact and Duration of Use
- Sterility Assurance Level and Method of Sterilization

The subject device and the predicate device are different in the following manner:

- A new accessory vacuum-initiated drainage kit, the PeritX™ Drainage Kit

7. Performance Testing Summary

To demonstrate substantial equivalence of the subject device to the predicate device, the technological characteristics and performance criteria were evaluated. Using internal risk assessment procedures based on ISO 14971:2019, “Medical Devices – Application of Risk Management to Medical Devices,” the following non-clinical tests were performed:

- Visual Inspection of Reference Marking Integrity
- Access Tip to Catheter Valve Tensile
- Corner Hole Tensile Strength
- Tubular Junctions Tensile Strength
- Snapper to Housing Tensile Strength
- Access Tip to Access Tip Protector Tensile Strength
- Volume Capacity
- Drop Test
- Resistance to Leakage During Aspiration or Vacuum
- Visual Inspection of Deformation
- Backflow Volume
- Flow Control Slider Use
- Access Tip to Catheter Valve Connection
- Tear Tab Use
- Packaging Validation
- Sterilization Testing

The results demonstrate that the technological characteristics and performance criteria of the PeritX™ Peritoneal Catheter System when used with the new accessory, the PeritX™ Drainage Kit are comparable to the predicate device and that it performs as safely and as effectively as the legally marketed predicate device.

8. Conclusion

The PeritX™ Peritoneal Catheter System is substantially equivalent to the legally marketed predicate device, the PeritX™ Peritoneal Catheter System (K201155; Clearance Date October 21, 2020).