December 8, 2023

Bard Peripheral Vascular, Inc.
Kristen Ortiz
Regulatory Affairs Manager
1625 W 3rd St
Tempe, Arizona 85281

Re: K232737
Trade/Device Name: PowerPort™ ClearVUE™ Slim ECG Enabled Implantable Port; PowerPort™ ClearVUE™ isp ECG Enabled Implantable Port; PowerPort™ isp M.R.I.™ ECG Enabled Implantable Port; PowerPort™ Slim ECG Enabled Implantable Port
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port And Catheter
Regulatory Class: Class II
Product Code: LJT
Dated: November 8, 2023
Received: November 8, 2023

Dear Kristen Ortiz:

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.

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,

David Wolloscheck

David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors

OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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.

Submission Number *(if known)*

K232737

Device Name

PowerPort™ ClearVUE™ Slim ECG Enabled Implantable Port;
PowerPort™ ClearVUE™ isp ECG Enabled Implantable Port;
PowerPort™ isp M.R.I.™ ECG Enabled Implantable Port;
PowerPort™ Slim ECG Enabled Implantable Port

Indications for Use *(Describe)*

The PowerPort™ Implantable Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications including anti-cancer medicines (chemotherapy), I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.
When used with the PowerLoc™ Safety Infusion Set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K232737 - ECG Enabled Implantable Ports Special 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:	602-830-5652
Fax:	312-949-0436
Contact:	Kristen Ortiz, Regulatory Affairs Manager
Date	December 8, 2023

Subject Device Name:

Device Trade Name:	PowerPort™ ClearVUE™ Slim ECG Enabled Implantable Port; PowerPort™ ClearVUE™ isp ECG Enabled Implantable Port; PowerPort™ isp M.R.I.™ ECG Enabled Implantable Port; PowerPort™ Slim ECG Enabled Implantable Port
Classification:	Class II
Regulation:	21 CFR 880.5965, Subcutaneous, implanted, intravascular infusion port and catheter
Review Panel:	General Hospital
Product Code:	LJT

Predicate Devices:

Predicate Device	Subject Device
PowerPort™ ClearVUE™ Slim Implantable Port (K122899, cleared 11/15/2012)	PowerPort™ ClearVUE™ Slim ECG Enabled Implantable Port
PowerPort™ Implanted Polymeric Port (K063377, cleared 1/25/2007)	PowerPort™ ClearVUE™ isp ECG Enabled Implantable Port; PowerPort™ isp M.R.I.™ ECG Enabled Implantable Port
Titanium PowerPort™ isp Implanted Port (K072549, cleared 11/14/2007)	PowerPort™ Slim ECG Enabled Implantable Port

Device Description:

The PowerPort™ implantable ports, including ECG Enabled Implantable Ports, are implantable access devices designed to provide repeated access to the vascular system. Port access is performed by percutaneous needle insertion using a non-coring needle. Power injection is performed using a PowerLoc™ Safety Infusion Set only. The PowerPort™ implantable port consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. Single lumen PowerPort™ implantable ports can be identified subcutaneously by feeling the top of the septum which includes three palpation bumps arranged in a triangle and by palpating the sides of the port, which is also triangular. Radiopaque identifiers for the PowerPort™ devices aid in identification as a BD power injectable port.

The ECG Enabled Implantable Ports function identically to other PowerPort™ power-injectable ports with the option to use ECG instead of fluoroscopy during the implantation procedure for catheter advancement and tip location confirmation using the BD Sherlock 3CG™ Tip Positioning System (TPS) stylet and BD Sherlock 3CG+™ Tip Confirmation System (TCS). ECG technology provides real-time catheter tip location information and is indicated for use as an alternative method to chest X-ray and fluoroscopy for central venous access device (CVAD) tip placement confirmation. When used with the BD Sherlock 3CG+™ TCS, the Sherlock 3CG™ TPS stylet also provides the placer real-time feedback on catheter tip location and orientation through the use of passive magnets and cardiac electrical signal detection. The Sherlock 3CG™ Tip Confirmation System (TCS) product and accessories are sold separately (refer to K180560, cleared 6/18/2018, for information on Sherlock 3CG+™ product and accessories).

Indications for Use of Device:

The PowerPort™ Implantable Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications including anti-cancer medicines (chemotherapy), I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

When used with the PowerLoc Safety Infusion Set, the PowerPort device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.

Comparison to Predicate Device:

Technological Characteristic	**Predicate Device** PowerPort™ ClearVUE™ Slim Implantable Port (K122899) PowerPort™ Implanted Polymeric Port (K063377) Titanium PowerPort™ isp Implanted Port (K072549)	**Subject Device** PowerPort™ ClearVUE™ Slim ECG Enabled Implantable Port PowerPort™ ClearVUE™ isp ECG Enabled Implantable Port; PowerPort™ isp M.R.I.™ ECG Enabled Implantable Port PowerPort™ Slim ECG Enabled Implantable Port	**Discussion**
Intended use	The PowerPort™ Implanted Port is a totally implantable vascular access device designed to provide long-term, repeated access to the vascular system.	Same	Same as Predicate
Indications for use	The PowerPort™ Implanted Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with the PowerLoc™ Safety Infusion Set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.	The PowerPort™ Implanted Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications **including anti-cancer medicines (chemotherapy)**, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with the PowerLoc™ Safety Infusion Set, the PowerPort™ device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.	The addition of “anti-cancer medicines (chemotherapy),” was cleared under K181446.
Patient population	Patients requiring repeated access to the vascular system	Same	Same as Predicate

Technological Characteristic	**Predicate Device**	**Subject Device**	**Discussion**
	PowerPort™ ClearVUE™ Slim Implantable Port (K122899)	PowerPort™ ClearVUE™ Slim ECG Enabled Implantable Port	
	PowerPort™ Implanted Polymeric Port (K063377)	PowerPort™ ClearVUE™ isp ECG Enabled Implantable Port; PowerPort™ isp M.R.I.™ ECG Enabled Implantable Port	
	Titanium PowerPort™ isp Implanted Port (K072549)	PowerPort™ Slim ECG Enabled Implantable Port	
Principle of operation	The device's primary components consist of a triangular injection port with self-sealing silicone septum and a radiopaque catheter. A simple sliding lock collar secures the catheter to the port's stem. The port can be identified through the patient skin via the three palpation bumps arranged in a triangle on the septum. Port access is performed by percutaneous needle insertion using a non-coring needle.	Same	Same as Predicate
Insertion site	Most commonly on upper chest	Same	Same as Predicate
Catheter tip termination location	Central venous system - lower 1/3 of superior vena cava preferred	Same	Same as Predicate
Duration of use	Long term (>30 days)	Same	Same as Predicate
Method of sterilization and sterility assurance level	Ethylene Oxide, 10^{-6}	Same	Same as Predicate
Visualization technique	Fluoroscopy	Fluoroscopy **or ECG**	The subject devices facilitate accurate reproduction of source ECG signals as shown by ECG Accuracy Verification Testing. Therefore, when used with the BD Sherlock 3CG+™ TCS, the subject devices can be used to

Technological Characteristic	**Predicate Device**	**Subject Device**	**Discussion**
	PowerPort™ ClearVUE™ Slim Implantable Port (K122899)	PowerPort™ ClearVUE™ Slim ECG Enabled Implantable Port	
	PowerPort™ Implanted Polymeric Port (K063377)	PowerPort™ ClearVUE™ isp ECG Enabled Implantable Port; PowerPort™ isp M.R.I.™ ECG Enabled Implantable Port	
	Titanium PowerPort™ isp Implanted Port (K072549)	PowerPort™ Slim ECG Enabled Implantable Port	
			facilitate catheter advancement and tip location confirmation using patient ECG. No new or different questions of safety and effectiveness are raised because the device can be accurately visualized using fluoroscopy or ECG.
ECG-compatible components	None	**Included, such as stylet that is used during catheter placement**	In addition to ECG Accuracy Verification testing, Catheter Air Leak and Usability testing were conducted to evaluate the functionality and acceptability of stylet use with the port catheter. All testing passed the predetermined acceptance criteria. No new or different questions of safety and effectiveness are raised because the device can be accurately placed using the stylet.
Packaging configuration	Triple tray packaging; two sterile barriers in the form of nested, sealed trays	**Organizational tray and retainer lid sealed inside a header bag**	Packaging validation testing evaluated the functionality and acceptability of the final product. All testing passed the predetermined acceptance criteria.
Device Dimensions			Changes to dimensions were qualified through the following performance tests. All testing passed the predetermined acceptance criteria. No new or different questions of safety and effectiveness are raised

Technological Characteristic	**Predicate Device**	**Subject Device**	**Discussion**
	PowerPort™ ClearVUE™ Slim Implantable Port (K122899)	PowerPort™ ClearVUE™ Slim ECG Enabled Implantable Port	
	PowerPort™ Implanted Polymeric Port (K063377)	PowerPort™ ClearVUE™ isp ECG Enabled Implantable Port; PowerPort™ isp M.R.I.™ ECG Enabled Implantable Port	
	Titanium PowerPort™ isp Implanted Port (K072549)	PowerPort™ Slim ECG Enabled Implantable Port	
			because the dimensional changes do not affect the device performance.
	<u>PowerPort™ ClearVUE™ Slim:</u> Height: 10.6 mm Width: 21.6 mm x 25.5 mm Reservoir Volume: 0.4 mL Catheter: 8 Fr x 46.4 cm, 1.6 mm ID	<u>PowerPort™ ClearVUE™ Slim:</u> Height: 10.**4** mm Width: 21.6 mm x 25.5 mm Reservoir Volume: 0.4 mL Catheter: 8 Fr x 46.4 cm, 1.6 mm ID **6 Fr x 46.4 cm, 1.3 mm ID**	<u>PowerPort™ ClearVUE™ Slim:</u> • Stem Catheter Leak • Stem Connection Tensile • Stem Catheter Burst • Port Subassembly Air Leak • Lateral Stem Tensile Strength • Port Subassembly Tensile Strength • Multiple Power Injections • Port System Burst, Power Injection • Port Subassembly Air Burst • Catheter Flow Rate
	<u>PowerPort™ Implanted Polymeric Port:</u> Height: 13.7 mm Width: 30.0 mm x 28.8 mm Reservoir Volume: 0.6 mL Catheter: 8 Fr x 46.4 cm, 1.6 mm ID	<u>PowerPort™ ClearVUE™ isp:</u> Height: **11.9 mm** Width: **24.4 mm x 25.9 mm** Reservoir Volume: 0.6 mL Catheter: 8 Fr x 46.4 cm, 1.6 mm ID **6 Fr x 46.4 cm, 1.3 mm ID**	<u>PowerPort™ ClearVUE™ isp:</u> • Stem Catheter Leak • Stem Connection Tensile • Stem Catheter Burst • Port Subassembly Air Leak • Port System Burst, Power Injection • Port Subassembly Tensile Strength • Multiple Power Injections • Port Subassembly Air

Technological Characteristic	**Predicate Device** PowerPort™ ClearVUE™ Slim Implantable Port (K122899) PowerPort™ Implanted Polymeric Port (K063377) Titanium PowerPort™ isp Implanted Port (K072549)	**Subject Device** PowerPort™ ClearVUE™ Slim ECG Enabled Implantable Port PowerPort™ ClearVUE™ isp ECG Enabled Implantable Port; PowerPort™ isp M.R.I.™ ECG Enabled Implantable Port PowerPort™ Slim ECG Enabled Implantable Port	**Discussion**
			• Burst • Catheter Flow Rate • Magnetic Resonance Imaging Compatibility
		<u>PowerPort™ isp M.R.I.™:</u> Height: **11.7 mm** Width: **23.7 mm x 26.6 mm** Reservoir Volume: 0.6 mL Catheter: 8 Fr x 46.4 cm, 1.6 mm ID **6 Fr x 46.4 cm, 1.3 mm ID**	<u>PowerPort™ isp M.R.I.™:</u> • Port Subassembly Tensile Strength • Port Subassembly Air Leak • Port Subassembly Air Burst • Septum Obturation • Multiple Power Injections • Port System Burst, Power Injection • Port System Injection Rate
	<u>Titanium PowerPort™ isp Implanted Port:</u> Height: 11.2 mm Width: 24.1 mm x 27.3 mm Reservoir Volume: 0.6 mL Catheter: 6.0 Fr x 45 cm, 1.3 mm ID	<u>PowerPort™ Slim:</u> Height: **9.8 mm** Base Width: **21.2 mm x 25.5 mm** Reservoir Volume: **0.5 mL** Catheter: 6.0 Fr x **61 cm**, 1.3 mm ID	<u>PowerPort™ Slim</u>: • Port Reservoir Height • Port Bottom Thickness • Port Subassembly Tensile Strength • Port Subassembly Air Leak • Septum Obturation • Multiple Power Injections • Port System Burst, Power Injection • Port System Injection Rate • Port Identification
Device Materials	<u>PowerPort™ ClearVUE™ Slim:</u> PEEK, silicone, Bi_2O_3/acetyl polymer	<u>PowerPort™ ClearVUE™ Slim:</u> Same	Same as Predicate

Technological Characteristic	**Predicate Device**	**Subject Device**	**Discussion**
	PowerPort™ ClearVUE™ Slim Implantable Port (K122899)	PowerPort™ ClearVUE™ Slim ECG Enabled Implantable Port	
	PowerPort™ Implanted Polymeric Port (K063377)	PowerPort™ ClearVUE™ isp ECG Enabled Implantable Port; PowerPort™ isp M.R.I.™ ECG Enabled Implantable Port	
	Titanium PowerPort™ isp Implanted Port (K072549)	PowerPort™ Slim ECG Enabled Implantable Port	
	<u>PowerPort™ Implanted Polymeric Port:</u> Delrin, silicone, titanium	<u>PowerPort™ ClearVUE™ isp:</u> Delrin, silicone, **Bi_2O_3/acetyl polymer**	Changes to PowerPort™ ClearVUE™ isp materials were qualified through the following performance tests. All testing passed the predetermined acceptance criteria. No new or different questions of safety and effectiveness are raised because the material changes do not affect the device performance. • Stem Catheter Leak • Stem Connection Tensile • Stem Catheter Burst • Port Subassembly Air Leak • Port System Burst, Power Injection • Port Subassembly Tensile Strength • Multiple Power Injections • Port Subassembly Air Burst • Catheter Flow Rate
		<u>PowerPort™ isp M.R.I.™:</u> Same	Same as Predicate
	<u>Titanium PowerPort™ isp Implanted Port:</u> Titanium, silicone	<u>PowerPort™ Slim:</u> Same	Same as Predicate
	<u>Catheter:</u> Chronoflex (purple) for Titanium PowerPort™ isp; Chronoflex (white) for all other ports	<u>Catheter (all ports):</u> Chronoflex (**white**)	The PowerPort™ Slim port catheter change was qualified through the following performance tests. All testing passed the

Technological Characteristic	**Predicate Device**	**Subject Device**	**Discussion**
	PowerPort™ ClearVUE™ Slim Implantable Port (K122899)	PowerPort™ ClearVUE™ Slim ECG Enabled Implantable Port	
	PowerPort™ Implanted Polymeric Port (K063377)	PowerPort™ ClearVUE™ isp ECG Enabled Implantable Port; PowerPort™ isp M.R.I.™ ECG Enabled Implantable Port	
	Titanium PowerPort™ isp Implanted Port (K072549)	PowerPort™ Slim ECG Enabled Implantable Port	
			predetermined acceptance criteria. No new or different questions of safety and effectiveness are raised because the material change does not affect the device performance. • Multiple Power Injections • Port System Burst, Power Injection • Port System Injection Rate
	<u>Cathlock (all ports):</u> Polycarbonate	<u>Cathlock (all ports):</u> Same	Same as Predicate
Shelf Life			Changes to shelf life were qualified through the following performance tests. All testing passed the predetermined acceptance criteria. No new or different questions of safety and effectiveness are raised because the device performance met requirements after shelf life testing.
	<u>PowerPort™ ClearVUE™ Slim:</u> 1.5 years	<u>PowerPort™ ClearVUE™ Slim:</u> **2 years**	<u>PowerPort™ ClearVUE™ Slim:</u> • Port System Burst, Power Injection • Septum Obturation • Needle Retention Tensile Strength • Port Subassembly Tensile Strength • Port Subassembly Air Leak

Technological Characteristic	**Predicate Device**	**Subject Device**	**Discussion**
	PowerPort™ ClearVUE™ Slim Implantable Port (K122899)	PowerPort™ ClearVUE™ Slim ECG Enabled Implantable Port	
	PowerPort™ Implanted Polymeric Port (K063377)	PowerPort™ ClearVUE™ isp ECG Enabled Implantable Port; PowerPort™ isp M.R.I.™ ECG Enabled Implantable Port	
	Titanium PowerPort™ isp Implanted Port (K072549)	PowerPort™ Slim ECG Enabled Implantable Port	
			• Port Subassembly Air Burst • Stem Catheter Leak • Stem Catheter Burst • Stem Connection Tensile • Multiple Power Injections • Catheter Flow Rate
	<u>PowerPort™ Implanted Polymeric Port:</u> 1 year	<u>PowerPort™ ClearVUE™ isp:</u> **2 years** <u>PowerPort™ isp M.R.I.™:</u> **2 years**	<u>PowerPort™ ClearVUE™ isp/PowerPort™ isp M.R.I.™:</u> • Catheter Air Burst • Catheter Tensile Strength • Flow Rate/Multiple Power Injection • Port System Burst, Power Injection • Septum Obturation • Needle Retention Tensile Strength • Port Subassembly Tensile Strength • Port Subassembly Air Leak • Port Subassembly Air Burst • Stem Catheter Leak • Stem Catheter Burst • Stem Connection Tensile • Port System Flow Rate
	<u>Titanium PowerPort™ isp Implanted Port:</u> 1 year	<u>PowerPort™ Slim:</u> **2 years**	<u>PowerPort™ Slim:</u> • Port System Injection Rate • Multiple Power Injections

Technological Characteristic	**Predicate Device**	**Subject Device**	**Discussion**
	PowerPort™ ClearVUE™ Slim Implantable Port (K122899)	PowerPort™ ClearVUE™ Slim ECG Enabled Implantable Port	
	PowerPort™ Implanted Polymeric Port (K063377)	PowerPort™ ClearVUE™ isp ECG Enabled Implantable Port; PowerPort™ isp M.R.I.™ ECG Enabled Implantable Port	
	Titanium PowerPort™ isp Implanted Port (K072549)	PowerPort™ Slim ECG Enabled Implantable Port	
			• Port System Burst, Power Injection

Performance Data:

To demonstrate substantial equivalence of the subject device to the predicate device, both technical characteristics and performance criteria were evaluated. Using FDA Guidance documents on non-clinical testing of medical devices and internal Risk Assessment procedures, tests for the following characteristics and performance criteria were evaluated for the subject device:

- Catheter Air Leak
- Packaging Validation
- Usability
- ECG Accuracy Verification
- Catheter Air Burst
- Catheter Flow Rate
- Catheter Tensile Strength
- Flow Rate/Multiple Power Injection
- Lateral Stem Tensile Strength
- Magnetic Resonance Imaging Compatibility
- Multiple Power Injections
- Needle Retention Tensile Strength
- Port Bottom Thickness
- Port Reservoir Height
- Port Subassembly Air Burst
- Port Subassembly Air Leak
- Port Subassembly Tensile Strength
- Port System Burst, Power Injection

- Port System Flow Rate
- Port System Injection Rate
- Septum Obturation
- Stem Catheter Burst
- Stem Catheter Leak
- Stem Connection Tensile
- Port Identification

These tests were performed in accordance with the following FDA Guidance and standards:

- *ASTM D4332, 2022: Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing*
- *ASTM D4169, 2022: Standard Practice for Performance Testing of Shipping Containers and Systems*
- *ISO 11607-1, 2019: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
- *FDA Guidance, Applying Human Factors and Usability Engineering to Medical Devices, February 2016*
- *Guidance on 510(k) Submissions for Implanted Infusion Ports, dated October 1990*
- *ASTM D 412 Rev 06a, Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers - Tension*
- *ISO 10555-1, 1995, Sterile, single-use intravascular catheters, Part 1. General requirements*
- *ISO 10555-3, 2002, Sterile, single-use intravascular catheters, Part 3. Central venous catheters*
- *NF S 94-370, French Standard, Surgical Implants, implantable catheter chambers, intravenous, intraarterial, intraperitoneal, intrathecal and epidural use (April 1999)*

The results from these tests demonstrate that the technical characteristics and performance criteria of the ECG Enabled Implantable Ports are substantially equivalent to the predicate devices and can perform in a manner equivalent to devices currently on the market for the same intended use.

Conclusion:

The subject device, the ECG Enabled Implantable Ports, met all predetermined acceptance criteria for design verification and validation activities as specified by applicable standards, guidance, test protocols and/or customer inputs.

Therefore, Bard Peripheral Vascular, Inc. concludes that the subject device, the ECG Enabled Implantable Port, is substantially equivalent to the legally marketed predicate devices.