October 31, 2024

Bard Access Systems, Inc.
Roessler Aaron
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, Utah 84116

Re: K242328
Trade/Device Name: PowerPort™ ClearVUE™ Slim Implantable Ports and PowerPort™ ClearVUE™ Slim Implantable Ports
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port And Catheter
Regulatory Class: Class II
Product Code: LJT
Dated: October 1, 2024
Received: October 1, 2024

Dear Roessler Aaron:

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,

Porsche Bennett,
For 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242328

Device Name
PowerPort™ ClearVUE™ Slim Implantable Ports and PowerPort™ ClearVUE™ Slim Implantable Ports

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™ Implantable Port 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.

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K242328. 510(K)SUMMARY

Submitter Information:

Applicant:	Bard Access Systems, Inc 605 North 5600 West Salt Lake City, UT 84116
Phone:	602-830-5612
Contact:	Aaron Roessler, Regulatory Affairs Specialist
Date	October 31, 2024

Subject Device Name:

Device Trade Name:	**PowerPort™ ClearVUE™ Slim Implantable Ports and PowerPort™ ClearVUE™ Slim Implantable Ports**
Classification:	Class II
Regulation:	21 CFR 880.5965, Subcutaneous, implanted, intravascular infusion port and catheter
Review Panel:	General Hospital
Product Code:	LJT

Predicate Devices:

PowerPort™ Implanted Polymeric Port (K063377, cleared 1/25/2007)

PowerPort™ ClearVUE™ Slim Implantable (K122899, cleared 11/15/2012)

Device Description:

The PowerPort™ Implantable Port is an implantable access device 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 may include three palpation bumps arranged in a triangle, and by palpating the sides of the port, which is also triangular. Dual lumen PowerPort™ Implantable Ports can be identified subcutaneously by feeling the top of each septum; each septum may feature three palpation bumps arranged in a triangle.

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 Implantable Port 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:

Table 1. Subject and Predicate Device Comparison – PowerPort™ ClearVUE™ Slim Implantable Port

Attribute	**Predicate Device** PowerPort™ ClearVUE™ Slim Implantable (K122899)	**Subject Device** PowerPort™ ClearVUE™ Slim Implantable Port	**Discussion**
Note	1. **Bold Font** indicates a difference between the subject device and predicate devices 2. Plain Type indicates that the attribute of the subject device is the same as that of the predicate device(s).		
Device Identification			
Manufacturer	Bard Access Systems, Inc.	Bard Access Systems, Inc.	**Same as Predicate**
Device Classification Name	Port & Catheter, Implanted, Subcutaneous, Intravascular	Port & Catheter, Implanted, Subcutaneous, Intravascular	**Same as Predicate**
Regulation Number	21 CFR §880.5965	21 CFR §880.5965	**Same as Predicate**
FDA Product Code	LJT	LJT	**Same as Predicate**
Device Use			
Intended Use	The PowerPort™ Implanted Port is a totally implantable vascular access device designed to provide long-term, repeated access to the vascular system.	The PowerPort™ Implanted Port is a totally implantable vascular access device designed to provide long-term, repeated access to the vascular system.	**Same as Predicate**
Indications for Use	The PowerPort® ClearVUE® Slim Implantable Port with 8F Polyurethane Catheter 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 a Powerloc® Safety Infusion Set (SIS), 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)[1]*, 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™ Implantable Port is indicated for power injection of contrast media. For power injection of contrast	**Different than Predicate**. The italicized clarifying statement was cleared for all PowerPorts™ in K181446, clearance date 07/08/2019.

Attribute	Predicate Device PowerPort™ ClearVUE™ Slim Implantable (K122899)	Subject Device PowerPort™ ClearVUE™ Slim Implantable Port		Discussion
		media, the maximum recommended infusion rate is 5 ml/s. [1]The italicized clarifying statement was cleared for all PowerPorts™ in K181446, clearance date 07/08/2019.		
Patient Population	Patients requiring repeated access to the vascular system	Patients requiring repeated access to the vascular system		**Same as Predicate**
Duration of Use	Long term (>30 days)	Long term (>30 days)		**Same as Predicate**
Insertion Site	Most commonly on upper chest	Most commonly on upper chest		**Same as Predicate**
Visualization Techniques	Fluoroscopy	Fluoroscopy		**Same as Predicate**
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.	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 as Predicate**
Catheter Tip Termination Location	Central venous system - lower 1/3 of superior vena cava preferred	Central venous system - lower 1/3 of superior vena cava preferred		**Same as Predicate**
Design Characteristics				
Device Measurements	**8 F** <u>Port Body:</u> Height: 10.6 mm Width: 21.6 mm x 25.5 mm Reservoir Volume: 0.4 mL	**8 F** <u>Port Body:</u> Height: **10.4 mm** Width: 21.6 mm x 25.5 mm Reservoir Volume: 0.4 mL	**6 F** <u>Port Body:</u> Height: **10.4 mm** Width: 21.6 mm x 25.5 mm Reservoir Volume: 0.4 mL	**Different than Predicate** The change in product dimensions did not change product performance. Labeling was updated for clarity only to ensure safer or more effective use. There were no changes to the indications for use, warnings, precautions or contraindications for the

Attribute	**Predicate Device** PowerPort™ ClearVUE™ Slim Implantable (K122899)	**Subject Device** PowerPort™ ClearVUE™ Slim Implantable Port		**Discussion**
				PowerPort™ ClearVUE™ Slim Implantable Port. There was no change in material composition, sterilization, or biocompatibility, so there was no change in safety or efficacy of the device. Performance testing was conducted on the to-be-marketed version of the subject device over the proposed shelf life to demonstrate the difference does not raise new questions of safety and effectiveness.
	Catheter: 8 Fr x 46.4 cm ChronoFlex, 1.6 mm ID	Catheter: 8 Fr x 46.4 cm ChronoFlex, 1.6 mm ID	**Catheter:** **6 Fr x 46.4 cm Chronoflex, 1.3 mm ID**	**Different than Predicate** The change in product dimensions did not change product performance. There were no changes to the indications for use, warnings, precautions or contraindications for the PowerPort™ ClearVUE™ Slim Implantable Port. There was no change in material composition, sterilization, or biocompatibility, so there was no change in safety or efficacy of the device. Performance testing was conducted on the to-be-marketed version of the subject device over the proposed shelf life to demonstrate the difference does not raise new questions of safety and effectiveness.

Device Description and Materials	Port Body: - Triangular hard plastic PEEK (polyetheretherketone) port cap and base, including stem - One-piece silicone septum with 3 raised palpation bumps - 3 suture holes with or without silicone suture plugs - Radiopaque bismuth trioxide (Bi_2O_3)/Delrin CT symbol captured between the cap and base assembly	Port Body: - Triangular hard plastic PEEK (polyetheretherketone) port cap and base, including stem - One-piece silicone septum with 3 raised palpation bumps - 3 suture holes with or without silicone suture plugs - Radiopaque bismuth trioxide (Bi_2O_3)/Delrin CT symbol captured between the cap and base assembly	**Same as Predicate**
	Catheter: - ChronoFlex - depth markings	Catheter: - ChronoFlex - depth markings	**Same as Predicate**
	Cathlock: - Polycarbonate	Cathlock: - Polycarbonate	**Same as Predicate**

Attribute	Predicate Device PowerPort™ ClearVUE™ Slim Implantable (K122899)	Subject Device PowerPort™ ClearVUE™ Slim Implantable Port	Discussion
Locking Solution	To help prevent clot formation and catheter blockage, each lumen of the implanted ports with open-ended catheters should be filled with sterile heparinized saline after each use. If the port remains unused for long periods of time, the heparin lock should be changed at least once every four weeks.	To help prevent clot formation and catheter blockage, each lumen of the implanted ports with open-ended catheters should be **flushed with sterile normal saline then filled with sterile heparinized saline, sterile normal saline, or other approved locking solution per institutional protocol after each use.** If the port remains unused for long periods of time, the lock should be changed at least once every 28 days. Warning: Alcohol should not be used to soak or declot polyurethane catheters because alcohol is known to degrade polyurethane catheters over time with repeated or prolonged exposure.	**Different from Predicate** Additional locking solutions to align with *Infusion Therapy Standards of Practice, 9th Edition* (2024). The device has the same intended use and this change does not raise questions of safety and effectiveness, so it is deemed that there is no impact to substantial equivalence due to this change.
Sterilization Method	Ethylene Oxide	Ethylene Oxide	**Same as Predicate**
Shelf Life	1.5 years	**2 years**	**Different than Predicate** Verification testing demonstrated that the device performed as intended by meeting product performance specifications and controlling risks to an acceptable level following aging and exposure to ethylene oxide sterilization and simulated shipping. Testing activities that were performed for the original 510(k) submission were conducted for the port configurations, such as port assembly leak, port assembly tensile, port assembly burst, lateral stem tensile, septum coring (needle obturation), port-catheter system multiple power injection, and

Attribute	**Predicate Device** PowerPort™ ClearVUE™ Slim Implantable (K122899)	**Subject Device** PowerPort™ ClearVUE™ Slim Implantable Port	**Discussion**
			port system burst (power injection). There was no change to indications for use, warnings, precautions, contraindications, sterilization, or biocompatibility. As such, there was no changes to device safety or effectiveness.
Packaging Configuration	Triple tray packaging; two sterile barriers in the form of nested, sealed trays	Triple tray packaging; two sterile barriers in the form of nested, sealed trays	**Same as Predicate**

Table 2. Subject and Predicate Device Comparison – PowerPort™ ClearVUE™ isp Implantable Port

Attribute	**Predicate Device** PowerPort™ Implanted Polymeric Port (K063377)	**Subject Device** PowerPort™ ClearVUE™ isp Implantable Port	**Discussion**
Note	1. **Bold Font** indicates a difference between the subject device and predicate devices 2. Plain Type indicates that the attribute of the subject device is the same as that of the predicate device(s).		
Device Identification			
Manufacturer	Bard Access Systems, Inc.	Bard Access Systems, Inc.	**Same as Predicate**
Device Classification Name	Port & Catheter, Implanted, Subcutaneous, Intravascular	Port & Catheter, Implanted, Subcutaneous, Intravascular	**Same as Predicate**
Regulation Number	21 CFR §880.5965	21 CFR §880.5965	**Same as Predicate**
FDA Product Code	LJT	LJT	**Same as Predicate**
Device Use			
Intended Use	The PowerPort™ Implanted Port is a totally implantable vascular access device designed to provide long-term, repeated access to the vascular system.	The PowerPort™ Implanted Port is a totally implantable vascular access device designed to provide long-term, repeated access to the vascular system.	**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	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)[1]*, 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™ Implantable Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.	**Different than Predicate.** The italicized clarifying statement was cleared for all PowerPorts™ in K181446, clearance date 07/08/2019.

Attribute	Predicate Device PowerPort™ Implanted Polymeric Port (K063377)	Subject Device PowerPort™ ClearVUE™ isp Implantable Port		Discussion
	recommended infusion rate is 5 ml/s.	[1]The italicized clarifying statement was cleared for all PowerPorts™ in K181446, clearance date 07/08/2019.		
Patient Population	Patients requiring repeated access to the vascular system	Patients requiring repeated access to the vascular system		**Same as Predicate**
Duration of Use	Long term (>30 days)	Long term (>30 days)		**Same as Predicate**
Insertion Site	Most commonly on upper chest	Most commonly on upper chest		**Same as Predicate**
Visualization Techniques	Fluoroscopy	Fluoroscopy		**Same as Predicate**
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.	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 as Predicate**
Catheter Tip Termination Location	Central venous system - lower 1/3 of superior vena cava preferred	Central venous system - lower 1/3 of superior vena cava preferred		**Same as Predicate**
Design Characteristics				
Device Measurements	**PowerPort M.R.I 8 F** <u>Port Body:</u>	**ClearVUE™ isp 8 F** **Port Body:**	**ClearVUE™ isp 6 F** **Port Body:**	**Different than Predicate** The change in product dimensions did not change product performance. Labeling

Attribute	Predicate Device PowerPort™ Implanted Polymeric Port (K063377)	Subject Device PowerPort™ ClearVUE™ isp Implantable Port		Discussion
	Height: 13.7mm Width: 30.0mm x Length: 28.8mm Reservoir Volume: 0.6mL	**Height: 11.9 mm** **Width: 24.4 mm 25.9 mm** Reservoir Volume: 0.6 mL	**Height: 11.9 mm** **Width: 24.4mm x 25.9 mm** Reservoir Volume: 0.6 mL	was updated for clarity only to insure safer or more effective use. There were no changes to the indications for use, warnings, precautions or contraindications for the PowerPort™ ClearVUE™ isp Implantable Port. There was no change in material composition, sterilization, or biocompatibility, so there was no change in safety or efficacy of the device. Performance testing was conducted on the to-be-marketed version of the subject device over the proposed shelf life to demonstrate the difference does not raise new questions of safety and effectiveness.
	Catheter: 8Fr x 45cm ChronoFlex	**Catheter:** **8 Fr x 46.4 cm ChronoFlex, 1.6 mm ID**	**Catheter:** **6 Fr x 46.4 cm ChronoFlex, 1.3 mm ID**	**Different than Predicate** The change in product dimensions did not change product performance. Labeling was updated for clarity only to insure safer or more effective use. There were no changes to the indications for use, warnings, precautions or contraindications for the PowerPort™ ClearVUE™ isp Implantable Port. There was no change in material composition, sterilization, or biocompatibility, so there was no change in safety or efficacy of the device. Performance testing was conducted on the to-be-marketed version of the subject device over the proposed shelf life to demonstrate the difference does not raise new questions of safety and effectiveness.
Device Description and Materials	**PowerPort M.R.I.**	**ClearVUE™ isp 8 F**	**ClearVUE™ isp 6 F**	**Different than Predicate** The “C T” symbol changed from titanium to

	Port Body: - Purple Triangular Delrin plastic port - radiopaque identifying feature displaying power injection symbol and the letters "C T" - one piece silicone septum - septum with 3 raised palpation bumps	Port Body: - Triangular Delrin plastic port **(with no colorant)** - radiopaque **non-metallic identifying feature** displaying power injection symbol and the letters "C T"	Port Body: - Triangular Delrin plastic port **(with no colorant)** - radiopaque identifying feature displaying power injection symbol and the letters "C T"	Delrin 500 NC-010 with 25% Bismuth Trioxide (Bi_2O_3); however, the new material is encapsulated and does not contact tissue or fluid. Encapsulation is achieved by dipping the CT symbol in a mixture of silicone thinned with hexane to create a thin skim-coat. The symbol is then assembled onto the port reservoir and the entire subassembly is over-molded in silicone. There was no change in sterilization and biocompatibility, and as such, there were no introduction or

Attribute	**Predicate Device** PowerPort™ Implanted Polymeric Port (K063377)	**Subject Device** PowerPort™ ClearVUE™ isp Implantable Port		**Discussion**
		- **Integral molded Delrin stem with two distal barbs** - one piece silicone septum - septum with 3 raised palpation bumps - **base is encapsulated**	- one piece silicone septum - septum with 3 raised palpation bumps	modification of risks associated with the final product.
	Catheter: - ChronoFlex polyurethane (with no colorant) - open-ended - single lumen - attachable	Catheter: - ChronoFlex polyurethane (with no colorant) - open-ended - single lumen - attachable	Catheter: - ChronoFlex polyurethane (with no colorant) - open-ended - single lumen - attachable	**Same as Predicate**
	Cathlock: - Polycarbonate	Cathlock: - Polycarbonate		**Same as Predicate**
Locking Solution	To help prevent clot formation and catheter blockage, each lumen of the implanted ports with open-ended catheters should be filled with sterile heparinized saline after each use. If the port remains unused for long periods of time, the heparin lock should be changed at least once every four weeks.	To help prevent clot formation and catheter blockage, each lumen of the implanted ports with open-ended catheters should be **flushed with sterile normal saline then filled with sterile heparinized saline, sterile normal saline, or other approved locking solution per institutional protocol after each use.** If the port remains unused for long periods of time, the lock should be changed at least once every 28 days.		**Different from Predicate** Additional locking solutions to align with *Infusion Therapy Standards of Practice, 9th Edition* (2024). The device has the same intended use and this change does not raise questions of safety and effectiveness, so it is deemed that there is no impact to substantial equivalence due to this change.

Attribute	**Predicate Device** PowerPort™ Implanted Polymeric Port (K063377)	**Subject Device** PowerPort™ ClearVUE™ isp Implantable Port	**Discussion**
		Warning: Alcohol should not be used to soak or declot polyurethane catheters because alcohol is known to degrade polyurethane catheters over time with repeated or prolonged exposure.	
Sterilization Method	Ethylene Oxide	Ethylene Oxide	**Same as Predicate**
Shelf Life	1 year	**2 years**	**Different than Predicate** Verification testing demonstrated that the device performed as intended by meeting product performance specifications and controlling risks to an acceptable level following aging and exposure to ethylene oxide sterilization and simulated shipping. Testing activities that were performed for the original 510(k) submission were conducted for the port configurations, including port assembly leak, port assembly tensile, port assembly burst, lateral stem tensile, septum coring (needle obturation), port-catheter system multiple power injection, and port system burst (power injection). As such, there was no changes to device safety or effectiveness.
Packaging Configuration	Triple tray packaging; two sterile barriers in the form of nested, sealed trays	Triple tray packaging; two sterile barriers in the form of nested, sealed trays	**Same as Predicate**

Design Verification:

Design verification testing was conducted to evaluate device performance over the proposed 2-year shelf life of the to-be-marketed configurations for all models of the subject device. Chemical conditioning was performed prior to testing to simulate the worst-case solutions used with ports and their components. Historical testing has been conducted and consisted of simulants used to account for the FDA approved oncology drugs, total parenteral nutrition (TPN) and vesicants used in intravascular access devices approved up to 2019. The testing evaluated the effects of the chemical simulants on silicone catheters as well as polyurethane catheters. It captures both medicines administrated, flushing solutions, and locking solutions. Material experts at BAS have confirmed the proposed locking solutions will not impact BAS catheters. The proposed locking solutions are within the pH range that will not impact the catheter materials. The functional testing with chemical conditioning demonstrates acceptable function of port devices. Studies evaluating these proposed solutions as well as guidelines of the use of these solutions in the field by health care providers are captured and summarized in the most recent Infusion Nurse Society guidelines, “Infusion Therapy Standards of Practice, revision 9”.

For changes, a Risk Assessment and Design Failure Mode and Effects Analysis (DFMEA) was used in accordance with internal procedures based on ISO 14971:2007, “Medical Devices – Application of Risk Management to Medical Devices,” to analyze the risks posed by the device changes and assure that risks posed by each device change were acceptable. No new risks were posed as a result of these changes.

Table 3: List of Verification/Validation Methods and Standards

Verification/Validation Method(s)	Standard/Guidance
Stem-Catheter Connection Air Leak Test	NF S 94-370 (1999)
Stem-Catheter Connection Tensile	NF S 94-370 (1999)
Stem-Catheter Air Burst	BAS Internal Test-Method
Port Subassembly Air Leak	FDA Implanted Infusion Port Guidance NF S 94-370 (1999)
Lateral Stem Tensile Strength	BAS Internal Test-Method
Port Subassembly Tensile Strength	BAS Internal Test-Method
Multiple Power Injections	BAS Internal Test-Method
Port System Burst, Power Injection	BAS Internal Test-Method
Catheter Flow Rate	ISO 10555-3 (2002) BAS Internal Test-Method
Septum Obturation	NF S 94-370 (1999)

Needle Retention Tensile Strength	NF S 94-370 (1999)
Stem Catheter Leak I	NF S 94-370 (1999)
Stem Catheter Leak II	NF S 94-370 (1999)
Stem Catheter Burst	BAS Internal Test-Method
Port Sub-assembly Air Burst	FDA Implanted Infusion Port Guidance
Catheter Air Burst	BAS Internal Test-Method
Catheter Tensile Strength	ISO 10555-1 (1995) ASTM D412
Port System Flow Rate	BAS Internal Test-Method

Conclusion:

The Bard Access Systems, Inc. concludes that the subject devices, the PowerPort™ ClearVUE™ Slim Implantable Ports and PowerPort™ ClearVUE™ isp Implantable Ports, are substantially equivalent to the legally marketed predicate devices.