September 5, 2025

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

Re: K252478
Trade/Device Name: Vaccess™ CT Low-Profile Power-Injectable Implantable Port; Vaccess™ CT Power-Injectable Implantable Port; PowerPort™ duo M.R.I. ™ 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: August 6, 2025
Received: August 7, 2025

Dear Kaitlyn Nielsen:

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,

David Wolloscheck -S

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)*
K252478

Device Name
Vaccess™ CT Low-Profile Power-Injectable Implantable Port;
Vaccess™ CT Power-Injectable Implantable Port;
PowerPort™ duo M.R.I. ™ Implantable Port

Indications for Use *(Describe)*
The Bard Power-Injectable 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 Bard Power-Injectable 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.

K252478 - 510(k) SUMMARY

Submitter Information

Applicant: Bard Access Systems, Inc
605 North 5600 West
Salt Lake City, UT 84116

Phone: 602-830-5681

Contact: Kaitlyn Nielsen, Regulatory Affairs Specialist

Date: August 25, 2025

Subject Device Name

Device Trade Name:	Vaccess™ CT Low-Profile Power-Injectable Implantable Port Vaccess™ CT Power-Injectable Implantable Port PowerPort™ duo M.R.I.™ Implantable Port
Common Name:	Subcutaneous, implanted, intravascular Port and Catheter
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™ Slim Implantable Port; PowerPort™ M.R.I.™ isp Implantable Port (K251253, cleared 06/18/2025)

PowerPort™ Duo M.R.I.™ Implanted Port with 9.5 Fr. Dual Lumen ChronoFlex™ Polyurethane Catheter (K090512, cleared 03/27/2009)

Reference Device

PowerPort™ ClearVUE™ isp Implantable Ports (K242328, cleared 10/31/2024)

Device Description

The Bard Power-Injectable 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 Bard Power-Injectable Implantable Port consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. Single lumen Bard Power-Injectable 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 Bard Power-Injectable 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 Bard Power-Injectable 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 Bard Power-Injectable 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 and Reference Device

The technological characteristics of the subject Bard Power-Injectable Implantable Port devices share many technological characteristics with the predicate devices. Among these shared technological characteristics are:

- Same intended use
- Same indications for use
- Same patient population
- Same principle of operation
- Same insertion site
- Same catheter tip termination location
- Same duration of use
- Same sterility assurance level and method of sterilization

- Same shelf life
- Same catheter locking solution options (Vaccess™ CT Implantable Ports)

Compared to the reference device, the subject devices have the following similarities:

- Device materials
- Additional catheter locking solution options (PowerPort™ duo Implantable Port)

Compared to the predicate devices, the subject devices have the following differences:

- Device dimensions

Table 1. Subject and Predicate Device Comparison – Vaccess™ CT Low-Profile Power-Injectable Implantable Port and Vaccess™ CT Power-Injectable Implantable Port

Attribute	Predicate Device PowerPort™ Slim Implantable Port (K251253) PowerPort™ M.R.I.™ isp Implantable Port (K251253)	Subject Device Vaccess™ CT Low-Profile Power-Injectable Implantable Port Vaccess™ CT Power-Injectable 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 Vaccess™ CT 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 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 Vaccess™ CT 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 Vaccess™ CT device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.	**Same as Predicate**
Patient Population	Patients requiring repeated access to the vascular system	Patients requiring repeated access to the vascular system	**Same as Predicate**

Attribute	Predicate Device PowerPort™ Slim Implantable Port (K251253) PowerPort™ M.R.I.™ isp Implantable Port (K251253)	Subject Device Vaccess™ CT Low-Profile Power-Injectable Implantable Port Vaccess™ CT Power-Injectable Implantable Port	Discussion
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. 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. 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	<u>PowerPort™ Slim Implantable Port:</u> *Port Body Dimensions:* Height: 9.8 mm Base Width: 21.2 mm x 25.5 mm Reservoir Volume: 0.5 mL <u>PowerPort™ M.R.I. ™ isp Implantable Port:</u> *Port Body:* Height: 11.7 mm Width: 23.7 mm x 26.6 mm	<u>Vaccess™ CT Low-Profile Power-Injectable Implantable Port:</u> *Port Body Dimensions:* Height: 9.8 mm Width**: 21.29 x 24.64** Reservoir Volume: 0.5 mL <u>Vaccess™ CT Power-Injectable Implantable Port:</u> *Port Body:* Height: 11.7mm Width: **23.6 mm x 26.7 mm**	**Different than Predicate** <u>Vaccess™ CT Low-Profile Power-Injectable Implantable Port:</u> The subject devices use the same material (titanium) as the predicate device, so all material evaluations for the predicate device are applicable to the subject device. <u>Vaccess™ CT Power-Injectable Implantable Port:</u> The subject devices use the same material (plastic) as the predicate device, so all material evaluations for the

Attribute	Predicate Device PowerPort™ Slim Implantable Port (K251253) PowerPort™ M.R.I.™ isp Implantable Port (K251253)	Subject Device Vaccess™ CT Low-Profile Power-Injectable Implantable Port Vaccess™ CT Power-Injectable Implantable Port	Discussion
	Reservoir Volume: 0.6 mL	Reservoir Volume: 0.6 mL	predicate device are applicable to the subject device. Sterilization and microbiology studies for both subject devices indicated that no new risks were introduced. The new dimensional specifications for the subject devices were qualified and fulfilled performance criteria. No changes were made to the intended use, indications, contraindications, warnings, precautions, or packaging of the final device.
	PowerPort™ Slim Implantable Port: *Catheter Dimensions:* 6 Fr x 60 cm ChronoFlex, 1.3 mm ID 8 Fr x 45 cm ChronoFlex, 1.6 mm ID PowerPort™ M.R.I. ™ isp Implantable Port: *Catheter Dimensions:* 6 Fr x 45 cm ChronoFlex, 1.3 mm ID 8 Fr x 45 cm ChronoFlex, 1.6 mm ID 9.6 Fr x 45cm Silicone, 1.6 mm ID	Vaccess™ CT Low-Profile Power-Injectable Implantable Port: *Catheter Dimensions:* 6 Fr x 60 cm ChronoFlex, 1.3 mm ID 8 Fr x 45 cm ChronoFlex, 1.6 mm ID Vaccess™ CT Power-Injectable Implantable Port: *Catheter Dimensions:* 6 Fr x 45 cm ChronoFlex, 1.3 mm ID 8 Fr x 45 cm ChronoFlex, 1.6 mm ID 9.6 Fr x 45 cm Silicone, 1.6 mm ID	**Same as Predicate**

Attribute	Predicate Device	Subject Device	Discussion
	PowerPort™ Slim Implantable Port (K251253)	Vaccess™ CT Low-Profile Power-Injectable Implantable Port	
	PowerPort™ M.R.I.™ isp Implantable Port (K251253)	Vaccess™ CT Power-Injectable Implantable Port	
Device Description and Materials	<u>PowerPort™ Slim Implantable Port:</u> *Port Body:* - Port Base: Titanium with engraved CT identification - Port Top: Titanium - One piece silicone septum with 3 raised palpation bumps - 3 suture holes with or without 3 suture plugs	<u>Vaccess™ CT Low-Profile Power-Injectable Implantable Port:</u> *Port Body:* - Port Base: Titanium with engraved CT identification - Port Top: Titanium - One piece silicone septum with **no** raised palpation bumps - 3 suture holes with or without 3 suture plugs	<u>Vaccess™ CT Low-Profile Power-Injectable Implantable Port:</u> **Same as Reference** The reference device does not have raised palpation bumps. The removal of palpation bumps does not introduce new hazards or failure modes. Palpation bumps are one of several identification methods for a power injectable port.
	<u>PowerPort™ M.R.I. ™ isp Implantable Port:</u> *Port Body:* - Purple Triangular Delrin plastic port - radiopaque identifying feature displaying power injection symbol and the letters "C T" - One piece silicone septum with 3 raised palpation bumps	<u>Vaccess™ CT Power-Injectable Implantable Port:</u> *Port Body:* - Triangular Delrin plastic port **(with no colorant)** - radiopaque identifying feature displaying power injection symbol and the letters "C T" - One piece silicone septum with **no** raised palpation bumps	<u>Vaccess™ CT Power-Injectable Implantable Port:</u> **Same as Reference** The Triangular Delrin body (with no colorant) has been previously used for the reference device. Since there was no substantial change in the material and design, pre-existing biocompatibility and sterilization evaluations were applicable to this change. There is no change in sterilization or biocompatibility. The reference device does not have raised palpation bumps. The removal of

Attribute	Predicate Device PowerPort™ Slim Implantable Port (K251253) PowerPort™ M.R.I.™ isp Implantable Port (K251253)	Subject Device Vaccess™ CT Low-Profile Power-Injectable Implantable Port Vaccess™ CT Power-Injectable Implantable Port	Discussion
			palpation bumps does not introduce new hazards or failure modes. Palpation bumps are one of several identification methods for a power injectable port.
	PowerPort™ Slim Implantable Port: *Catheter:* - White ChronoFlex polyurethane - open-ended - with depth markings - single lumen - attachable PowerPort™ M.R.I. ™ isp Implantable Port: *Catheter:* - White ChronoFlex polyurethane - open-ended - with depth markings - single lumen - attachable Silicone Catheter - open-ended - with depth markings - single lumen - attachable	Vaccess™ CT Low-Profile Power-Injectable Implantable Port: *Catheter:* - White ChronoFlex polyurethane - open-ended - with depth markings - single lumen - attachable Vaccess™ CT Power-Injectable Implantable Port: *Catheter:* - White ChronoFlex polyurethane - open-ended - with depth markings - single lumen - attachable Silicone Catheter - open-ended - with depth markings - single lumen - attachable	**Same as Predicate**
	Cathlock: Polycarbonate	Cathlock: Polycarbonate	**Same as Predicate**
Locking Solution	Open-ended catheters:	Open-ended catheters:	**Same as Predicate**

Attribute	Predicate Device PowerPort™ Slim Implantable Port (K251253) PowerPort™ M.R.I.™ isp Implantable Port (K251253)	Subject Device Vaccess™ CT Low-Profile Power-Injectable Implantable Port Vaccess™ CT Power-Injectable Implantable Port	Discussion
	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.	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.	
Sterilization Method	Ethylene Oxide	Ethylene Oxide	**Same as Predicate**
Shelf Life	2 years	2 years	**Same as Predicate**
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™ duo M.R.I.™ Implantable Port

Attribute	**Predicate Device** PowerPort™ duo M.R.I. ™ Implanted Port with 9.5 Fr. Dual Lumen ChronoFlex™ Polyurethane Catheter (K090512)	**Subject Device** PowerPort™ duo M.R.I. ™ Implantable Port with Attachable 9.5F ChronoFlex™ Open-Ended Dual-Lumen Venous Catheter	**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 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™ device 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 Bard Power-Injectable Implantable Ports in K181446, clearance date 07/08/2019.

Attribute	**Predicate Device** PowerPort™ duo M.R.I. ™ Implanted Port with 9.5 Fr. Dual Lumen ChronoFlex™ Polyurethane Catheter (K090512)	**Subject Device** PowerPort™ duo M.R.I. ™ Implantable Port with Attachable 9.5F ChronoFlex™ Open-Ended Dual-Lumen Venous Catheter	**Discussion**
		[1]The italicized clarifying statement was cleared for all Bard Power-Injectable Implantable Ports 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. 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. 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	<u>Port Body:</u> Length: 38.5 mm Width: 28.5 mm Height: 12.6 mm Reservoir Volume: 0.6 mL per reservoir	<u>Port Body:</u> Length: **Max 39.1 mm** Width: **Max 29.2 mm** Height: **12.5 mm** Reservoir Volume: 0.6 mL per reservoir	**Different than Predicate** The change in product dimensions did not change product performance and met the same product performance specifications. 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 PowerPort™ duo M.R.I.™

Attribute	**Predicate Device** PowerPort™ duo M.R.I. ™ Implanted Port with 9.5 Fr. Dual Lumen ChronoFlex™ Polyurethane Catheter (K090512)	**Subject Device** PowerPort™ duo M.R.I. ™ Implantable Port with Attachable 9.5F ChronoFlex™ Open-Ended Dual-Lumen Venous Catheter	**Discussion**
			Implantable Port. There was no change in material composition, sterilization, or biocompatibility, so there was no change in safety or efficacy of the device.
	Catheter: Outside Diameter: 9.5 Fr Inner Diameter: 1.5 mm Catheter Length: 45 cm	Catheter: Outer Diameter: 9.5 Fr Inner Diameter: 1.5 mm Catheter Length: 45 cm	**Same as Predicate**
Device Description and Materials	Port Body: - Purple Triangular Delrin plastic port - radiopaque identifying feature displaying power injection symbol and the letters "C T" - Two silicone septa - septum with 3 raised palpation bumps	Port Body: - Purple Triangular Delrin plastic port - radiopaque identifying feature displaying power injection symbol and the letters "C T" - Two silicone septa - septum with 3 raised palpation bumps	**Same as Predicate**
	Catheter: - ChronoFlex™ polyurethane (with no colorant) - Open-ended - Dual lumen - Attachable	Catheter: - ChronoFlex™ polyurethane (with no colorant) - Open-ended - Dual 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	To help prevent clot formation and catheter blockage, each lumen of the implanted ports with open-ended catheters should be	**Same as Reference** Additional locking solutions to align with *Infusion Therapy*

Attribute	**Predicate Device** PowerPort™ duo M.R.I. ™ Implanted Port with 9.5 Fr. Dual Lumen ChronoFlex™ Polyurethane Catheter (K090512)	**Subject Device** PowerPort™ duo M.R.I. ™ Implantable Port with Attachable 9.5F ChronoFlex™ Open-Ended Dual-Lumen Venous Catheter	**Discussion**
	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.	**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.	*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	3 years and 4 months shelf life	3 years and 4 months shelf life	**Same as Predicate**
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**

Discussion of Differences

Alternative locking solutions

Vascular access devices (VAD) including implantable ports are flushed (usually with saline) prior to each use to assess catheter function and to help prevent complications. After use is concluded and the final flush, each VAD catheter lumen is locked with a locking solution to decrease the risk of lumen occlusion. The VAD lumen is filled with enough locking solution to fill the entire port system including the full length of the catheter and deaccessed with positive pressure to reduce the potential for blood backflow into the catheter.

While the predicate devices are limited to being locked with heparinized saline, the subject devices with open-ended catheters allow the option to use sterile normal saline or other approved locking solution per institutional protocol. *Infusion Therapy Standards of Practice, 9th Edition* (2024), which provides standards of practice for infusion nurses, states that "In adults, randomized controlled trials (RCTs) and systematic reviews have shown equivalent outcomes with heparin and sodium chloride lock solutions for multilumen, nontunneled CVADs, peripherally inserted central catheters (PICCs), and implanted vascular access ports while accessed and when the access needle is removed." Also described in the *Infusion Therapy Standards of Practice, 9th Edition* (2024) is the use of other locking solutions: "Change to an alternative locking solution when the heparin lock solution is thought to be the cause of adverse drug reactions from heparin; when heparin-induced thrombocytopenia and thrombosis (HITT) develops; and when there are spurious laboratory studies drawn from the CVAD that has been locked with heparin." Examples of alternative locking solutions listed in this article are antimicrobial and antiseptic locking solutions (sodium bicarbonate, taurolidine, citrate, concentrated sodium chloride, and ethylenediaminetetraacetic acid). It is ultimately the physicians' judgement on what locking solution is best for the patient. It is important to note that although alcohol has been known to be used as an antiseptic locking solution, some of our catheters are incompatible with this solution and a clear warning to avoid using alcohol to soak or declot polyurethane catheters has been added to the lock procedure in the IFU.

The intended users of Bard Power-Injectable Implantable Ports rely on these standards of practice for their institutional protocols. The goal is to ensure that Bard Power-Injectable Implantable Ports can continue to be used by users with the most up to date locking standard of practices.

This exact locking solution procedure update was cleared for the reference device PowerPort™ ClearVUE™ Implantable Ports (K242328, cleared 10/31/2024) and the predicate device

PowerPort™ Slim Implantable Port and PowerPort™ M.R.I.™ isp Implantable Port (K251253, cleared 18 June 2025).

Dimensional Changes

The subject devices use the same materials as the predicate devices, so all material evaluations for the predicate devices are applicable to the subject devices. Sterilization and microbiology studies indicated that no new risks were introduced. The new dimensional specifications for the product were qualified and fulfilled performance criteria. No changes were made to the intended use, indications, contraindications, warnings, precautions, or packaging of the final device.

Design Verification

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. Chemical conditioning was performed prior to testing to simulate the worst-case solutions used with ports and their components. 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. 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”.

Table 3. List of Verification/Validation Methods and Standards

Verification/Validation Method(s)	Standard/Guidance
Port Subassembly Air Burst	FDA Port Guidance
Port Subassembly Tensile Strength	BAS Internal

Conclusion

Bard Access Systems, Inc. concludes that the subject devices, Vaccess™ CT Low-Profile Power-Injectable Implantable Port, Vaccess™ CT Power-Injectable Implantable Port, and PowerPort™ duo M.R.I.™ Implantable Port are substantially equivalent to the legally marketed predicate devices.