June 18, 2025

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

Re: K251253
Trade/Device Name: PowerPort™ isp Implantable Port; PowerPort™ Slim Implantable Port; PowerPort™ M.R.I. ™ Implantable Port; PowerPort™ M.R.I.™ isp 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: May 20, 2025
Received: May 20, 2025

Dear Aaron Roessler:

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K251253

Device Name
PowerPort™ isp Implantable Port; PowerPort™ Slim Implantable Port; PowerPort™ M.R.I.™ Implantable Port; and PowerPort™ M.R.I.™ isp 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.

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# K251253 - 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 II

Date June 17, 2025

## Subject Device Name:

| | |
|---|---|
| Device Trade Name: | PowerPort™ isp Implantable Port<br>PowerPort™ Slim Implantable Port<br>PowerPort™ M.R.I.™ Implantable Port<br>PowerPort™ M.R.I.™ isp 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:

Titanium PowerPort™ isp Implanted Port with 6Fr ChronoFlex™ Polyurethane Catheter (K072549, cleared 11/14/2007)

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

## Reference Device:

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

## 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 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 and Reference Device:**

The technological characteristics of the subject PowerPort™ Implantable Port devices share many technological characteristics with the predicate and reference 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
- Device dimensions and materials

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

- Additional catheter locking solution options
- 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
- Device materials

## *Table 1. Subject and Predicate Device Comparison – Titanium PowerPort™ Implantable Port*

| **Attribute** | **Predicate Device** Titanium PowerPort™ isp Implanted Port with 6Fr ChronoFlex™ Polyurethane Catheter (K072549) | **Subject Device** PowerPort™ isp Implantable Port | **Subject Device** PowerPort™ Slim Implantable Port | **Discussion** |
|---|---|---|---|---|
| Note | 1. **Bold Font** indicates a difference between the subject device and historical predicate devices<br>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. | 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.<br><br>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. | | **Same as Reference Device and Currently Marketed Predicate**<br><br>**Different than Historical Predicate***<br>*The italicized clarifying statement was cleared for all PowerPort™ implantable ports in K181446, clearance date 07/08/2019. |

| **Attribute** | **Predicate Device** Titanium PowerPort™ isp Implanted Port with 6Fr ChronoFlex™ Polyurethane Catheter (K072549) | **Subject Device** PowerPort™ isp Implantable Port | **Subject Device** PowerPort™ Slim Implantable Port | **Discussion** |
|---|---|---|---|---|
| | 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. | [1]The italicized clarifying statement was cleared for all PowerPort™ 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. The port can be identified through the patient skin via the three palpation bumps arranged in a triangle on the septum. | 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.<br><br>Port access is performed by percutaneous needle insertion using a non-coring needle. | | **Same as Predicate** |

| **Attribute** | **Predicate Device** Titanium PowerPort™ isp Implanted Port with 6Fr ChronoFlex™ Polyurethane Catheter (K072549) | **Subject Device** PowerPort™ isp Implantable Port | **Subject Device** PowerPort™ Slim Implantable Port | **Discussion** |
|---|---|---|---|---|
| | Port access is performed by percutaneous needle insertion using a non-coring needle. | | | |
| *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* | Port Body Dimensions:<br>Height: 11.2 mm<br>Base Width: 24.1 mm x 27.3 mm<br>Reservoir Volume: 0.6 mL | Port Body Dimensions:<br>Height: 11.2 mm<br>Base Width: 24.1 mm x 27.3 mm<br>Reservoir Volume: 0.6 ml | Port Body:<br>Height: **9.8 mm**<br>Base Width: **21.2 mm x 25.5 mm**<br>Reservoir Volume: **0.5 mL** | **Same as Currently Marketed Predicate Device**<br><br>**Different than Historical Predicate**<br>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. 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, |

| Attribute | **Predicate Device** Titanium PowerPort™ isp Implanted Port with 6Fr ChronoFlex™ Polyurethane Catheter (K072549) | **Subject Device** PowerPort™ isp Implantable Port | **Subject Device** PowerPort™ Slim Implantable Port | **Discussion** |
|---|---|---|---|---|
| | | | | precautions, or packaging of the final device. |
| | Catheter Dimensions:<br>6F x 45 cm, 1.3 mm ID | Catheter:<br>6 Fr x **60 cm** Chronoflex, 1.3 mm ID<br>***8F x 45 cm Groshong, 1.5mm ID[2]***<br>***8 Fr x 45cm ChronoFlex, 1.6 mm ID[3]***<br><br>[2]Groshong catheters were cleared for use with titanium ports in K081311, clearance date 06/04/2008<br><br>[3]8F ChronoFlex catheters were cleared for use with titanium ports in K060812, clearance date 07/14/2006 | Catheter Dimensions:<br>6.0 Fr x **60 cm** ChronoFlex, 1.3 mm ID<br>***8F x 45 cm Groshong, 1.5mm ID[2]***<br>***8F x 45 cm ChronoFlex, 1.6mm ID[3]***<br><br>[2]Groshong catheters were cleared for use with titanium ports in K081311, clearance date 06/04/2008<br><br>[3]8F ChronoFlex catheters were cleared for use with titanium ports in K060812, clearance date 07/14/2006 | **Same as Currently Marketed Predicate Device**<br><br>**Different than Historical Predicate***<br>The long white ChronoFlex polyurethane catheter (no colorant) has been previously used for non-power injectable ports. 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. Performance verification and validation cleared the new catheter for power-injection use and demonstrated that no new risks were introduced or modified.<br>*Groshong catheters were cleared for use with titanium ports in K081311, clearance date 06/04/2008 |

| Attribute | **Predicate Device** Titanium PowerPort™ isp Implanted Port with 6Fr ChronoFlex™ Polyurethane Catheter (K072549) | **Subject Device** PowerPort™ isp Implantable Port | **Subject Device** PowerPort™ Slim Implantable Port | **Discussion** |
|---|---|---|---|---|
| | | | | *8F ChronoFlex catheters were cleared for use with titanium ports in K060812, clearance date 07/14/2006 |
| *Device Description and Materials* | Port Body:<br>- Port Base: Titanium with engraved CT identification<br>- Port Top: Titanium<br>- one piece silicone septum with 3 raised palpation bumps<br>- 3 suture holes with 3 suture plugs | Port Body:<br>- Port Base: Titanium with engraved CT identification<br>- Port Top: Titanium<br>- one piece silicone septum with or without 3 raised palpation bumps,<br>- 3 suture holes with 3 suture plugs | | **Same as Predicate** |
| | Catheter:<br>- **Purple** ChronoFlex polyurethane<br>- open-ended<br>- with depth markings<br>- single lumen<br>- attachable | Catheter:<br>- **White** ChronoFlex polyurethane **(no colorant)**<br>- open-ended<br>- with depth markings<br>- single lumen<br>- attachable<br><br>***Groshong silicone catheter - Close valved[2]***<br>- with depth markings<br>- single lumen<br>- attachable<br><br>[2]Groshong catheters were cleared for use with titanium ports in K081311, clearance date 06/04/2008 | Catheter:<br>- **White** ChronoFlex polyurethane **(no colorant)**<br>- open-ended<br>- with depth markings<br>- single lumen<br>- attachable<br><br>***Groshong silicone catheter - Close valved[2]***<br>- with depth markings<br>- single lumen<br>- attachable<br><br>[2]Groshong catheters were cleared for use with titanium ports in K081311, clearance date 06/04/2008 | **Same as Reference Device and Currently Marketed Predicate Device**<br><br>**Different than Historical Predicate Device**<br>The material difference was a historical change in which the only difference between the purple ChronoFlex polyurethane and the white ChronoFlex polyurethane is the removal of the purple colorant. Otherwise the materials are exactly the same. The long white ChronoFlex polyurethane catheter has been |

| Attribute | **Predicate Device** Titanium PowerPort™ isp Implanted Port with 6Fr ChronoFlex™ Polyurethane Catheter (K072549) | **Subject Device** PowerPort™ isp Implantable Port | **Subject Device** PowerPort™ Slim Implantable Port | **Discussion** |
|---|---|---|---|---|
| | | | | previously used for implantable ports including the reference device K242328. Since there was no substantial change in the material and design, pre-existing biocompatibility and sterilization evaluations were applicable to this change. <u>There is no change in sterilization or biocompatibility.</u> Historical performance verification and validation cleared the new catheter for power-injection use and demonstrated that no new risks were introduced or modified.<br><br>*Groshong catheters were cleared for use with titanium ports in K081311, clearance date 06/04/2008 |
| | <u>Cathlock:</u><br>Polycarbonate | <u>Cathlock:</u><br>Polycarbonate | | **Same as Predicate** |
| *Locking Solution* | <u>Open-ended catheters:</u><br>To help prevent clot formation and catheter blockage, each lumen of the implanted ports with open-ended catheters | <u>Open-ended catheters:</u><br>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 | | **Same as Reference**<br>The reference device PowerPort™ ClearVUE™ Implantable Ports was cleared for this exact same locking solution procedure |

| **Attribute** | **Predicate Device** Titanium PowerPort™ isp Implanted Port with 6Fr ChronoFlex™ Polyurethane Catheter (K072549) | **Subject Device** PowerPort™ isp Implantable Port | **Subject Device** PowerPort™ Slim Implantable Port | **Discussion** |
|---|---|---|---|---|
| | 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. | the port remains unused for long periods of time, the lock should be changed at least once every 28 days.<br><br>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.<br><br>***Groshong Catheters:***<br>***To help prevent clot formation and catheter blockage, implanted ports with Groshong™ Catheters should be filled with sterile normal saline after each use. If the port remains unused for long periods of time, the saline lock should be changed by flushing at least once every 90 days.***<br><br>*The Groshong catheter maintenance protocol was cleared for Groshong catheters in K133335, clearance date 02/14/2014 | | in K242328, clearance date 10/31/2024.<br><br>**Different from Predicate**<br>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.<br><br>*The Groshong catheter maintenance protocol was cleared for Groshong catheters in K133335, clearance date 02/14/2014 |
| *Sterilization Method* | Ethylene Oxide | Ethylene Oxide | | **Same as Predicate** |
| *Shelf Life* | 1 year | **2 years** | | **Different than Predicate**<br>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 |

| **Attribute** | **Predicate Device** Titanium PowerPort™ isp Implanted Port with 6Fr ChronoFlex™ Polyurethane Catheter (K072549) | **Subject Device** PowerPort™ isp Implantable Port | **Subject Device** PowerPort™ Slim Implantable Port | **Discussion** |
|---|---|---|---|---|
| | | | | assembly burst, lateral stem tensile, septum coring (needle obturation), port-catheter system multiple power injection, and port system burst (power injection). 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. 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 – Plastic PowerPort™ Implantable Port*

| **Attribute** | **Predicate Device** PowerPort™ Implanted Polymeric Port (K063377, cleared 1/25/2007) | **Subject Device** PowerPort™ M.R.I. ™ Implantable Port | **Subject Device** PowerPort™ M.R.I.™ isp Implantable Port | **Discussion** |
|---|---|---|---|---|
| Note | 1. **Bold Font** indicates a difference between the subject device and historical predicate devices<br>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. | 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.<br><br>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. | | **Same as Reference Device and Currently Marketed Device**<br><br>**Different than Historical Predicate***<br>*The italicized clarifying statement was cleared for all PowerPort™ implantable ports in K181446, clearance date 07/08/2019. |

| **Attribute** | **Predicate Device** PowerPort™ Implanted Polymeric Port (K063377, cleared 1/25/2007) | **Subject Device** PowerPort™ M.R.I. ™ Implantable Port | **Subject Device** PowerPort™ M.R.I.™ isp Implantable Port | **Discussion** |
|---|---|---|---|---|
| | 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. | [1]The italicized clarifying statement was cleared for all PowerPort™ 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. The port can be identified through the patient skin via the three palpation bumps arranged in a triangle on the septum. | 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.<br><br>Port access is performed by percutaneous needle insertion using a non-coring needle. | | **Same as Predicate** |

| Attribute | **Predicate Device** PowerPort™ Implanted Polymeric Port (K063377, cleared 1/25/2007) | **Subject Device** PowerPort™ M.R.I. ™ Implantable Port | **Subject Device** PowerPort™ M.R.I.™ isp Implantable Port | **Discussion** |
|---|---|---|---|---|
| | Port access is performed by percutaneous needle insertion using a non-coring needle. | | | |
| *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* | Port Body:<br>Height: 13.7mm<br>Width: 30.0mm x Length: 28.8mm<br>Reservoir Volume: 0.6mL<br><br>Catheter:<br>8Fr x 45 cm ChronoFlex, 1.6 mm ID | Port Body:<br>Width: 30.0mm<br>Length: 28.9mm<br>Height: 13.6mm<br>Reservoir Volume: 0.6mL<br><br>Catheter:<br>8F x 45cm ChronoFlex, 1.6 mm ID<br>**6 Fr x 45 cm Chronoflex, 1.3 mm ID**<br>***8Fr x 45cm Groshong, 1.5 mm ID[2]***<br><br>***9.6F x 45cm Silicone, 1.6 mm ID[4]***<br><br>[2]Groshong catheters were cleared for use with titanium ports in K081311, clearance date 06/04/2008<br><br>[4]Silicone catheters were cleared for use in PowerPort | Port Body:<br>Height: **11.7 mm**<br>Width: **23.7 mm x 26.6 mm**<br>Reservoir Volume: 0.6 mL<br><br>Catheter:<br>8 Fr x 45cm ChronoFlex, 1.6 mm ID<br>**6 Fr x 45 cm Chronoflex, 1.3 mm ID**<br>***8Fr x 45cm Groshong, 1.5 mm ID[2]***<br><br>***9.6F x 45cm Silicone, 1.6 mm ID[4]***<br>[2]Groshong catheters were cleared for use with titanium ports in K081311, clearance date 06/04/2008<br><br>[4]Silicone catheters were cleared for use in PowerPort implantable ports in K073423, clearance date 12/19/2007 | **Same as Currently Marketed Predicate Device**<br><br>**Different than Historical Predicate***<br>PowerPort™ M.R.I.™ isp Implantable Port<br>The change in product dimensions did not change product performance and the product met the same 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™ Implantable Port. There was no change in material composition, sterilization, or biocompatibility, so there |

| **Attribute** | **Predicate Device** PowerPort™ Implanted Polymeric Port (K063377, cleared 1/25/2007) | **Subject Device** PowerPort™ M.R.I. ™ Implantable Port | **Subject Device** PowerPort™ M.R.I.™ isp Implantable Port | **Discussion** |
|---|---|---|---|---|
| | | implantable ports in K073423, clearance date 12/19/2007 | | was no change in safety or efficacy of the device.<br><br>*Groshong catheters were cleared for use with titanium ports in K081311, clearance date 06/04/2008<br><br>*Silicone catheters were cleared for use in PowerPort implantable ports in K073423, clearance date 12/19/2007 |
| *Device Description and Materials* | Port Body:<br>- Purple Triangular Delrin plastic port<br>- radiopaque identifying feature displaying power injection symbol and the letters "C T"<br>- one piece silicone septum<br>- septum with 3 raised palpation bumps | Port Body:<br>- Purple Triangular Delrin plastic port<br>- radiopaque identifying feature displaying power injection symbol and the letters "C T"<br>- one piece silicone septum<br>- septum with 3 raised palpation bumps | Port Body:<br>- Purple Triangular Delrin plastic port<br>- radiopaque identifying feature displaying power injection symbol and the letters "C T"<br>- one piece silicone septum<br>- septum with 3 raised palpation bumps | **Same as Predicate Device** |
| | Catheter:<br>- **Purple** ChronoFlex polyurethane<br>- open-ended<br>- single lumen | Catheter:<br>- **White** ChronoFlex polyurethane **(no colorant)**<br>- open-ended<br>- with depth markings | Catheter:<br>- **White** ChronoFlex polyurethane **(no colorant)**<br>- open-ended<br>- with depth markings | **Same as Reference device and Currently Marketed Predicate Device** |

| **Attribute** | **Predicate Device**<br>PowerPort™ Implanted Polymeric Port (K063377, cleared 1/25/2007) | **Subject Device**<br>PowerPort™<br>M.R.I. ™ Implantable Port | **Subject Device**<br>PowerPort™ M.R.I.™ isp Implantable Port | **Discussion** |
|---|---|---|---|---|
| | - attachable | - single lumen<br>- attachable<br><br>***Groshong silicone catheter - Close valved[2]***<br>- with depth markings<br>- single lumen<br>- attachable<br><br>[2]Groshong catheters were cleared for use with titanium ports in K081311, clearance date 06/04/2008 | - single lumen<br>- attachable<br><br>***Groshong silicone catheter - Close valved[2]***<br>- with depth markings<br>- single lumen<br>- attachable<br><br>[2]Groshong catheters were cleared for use with titanium ports in K081311, clearance date 06/04/2008 | **Different than Historical Predicate Device***<br>The material difference was a historical change in which the only difference between the purple ChronoFlex polyurethane and the white ChronoFlex polyurethane is the removal of the purple colorant. Otherwise, the materials are exactly the same.The white ChronoFlex polyurethane catheter has been previously used for other implantable ports including the reference device K242328. Since there was no substantial change in the material and design, pre-existing biocompatibility and sterilization evaluations were applicable to this change. <u>There is no change in sterilization or biocompatibility.</u> Historical performance verification and validation cleared the new catheter for power-injection use and demonstrated that no new risks were introduced or modified.<br><br>*Groshong catheters were cleared for use with titanium |

| **Attribute** | **Predicate Device**<br>PowerPort™ Implanted Polymeric Port (K063377, cleared 1/25/2007) | **Subject Device**<br>PowerPort™<br>M.R.I. ™ Implantable Port | **Subject Device**<br>PowerPort™ M.R.I.™ isp Implantable Port | **Discussion** |
|---|---|---|---|---|
| | | | | ports in K081311, clearance date 06/04/2008<br><br>*Silicone catheters were cleared for use in PowerPort implantable ports in K073423, clearance date 12/19/2007 |
| | Cathlock:<br>Polycarbonate | Cathlock:<br>Polycarbonate | | **Same as Predicate** |
| *Locking Solution* | Open-ended Catheters:<br>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. | Open-ended Catheters:<br>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<br>once every 28 days.<br><br>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.<br><br>***Groshong Catheters:***<br>***To help prevent clot formation and catheter blockage, implanted ports with Groshong™ Catheters should be filled with sterile normal saline after each use. If the port remains unused for long periods of time, the saline lock should be changed by flushing at least once every 90 days.***<br><br>*The Groshong catheter maintenance protocol was cleared for Groshong catheters in K133335, clearance date 02/14/2014 | | **Same as Reference**<br>The reference device PowerPort™ ClearVUE™ Implantable Ports was cleared for this exact same locking solution procedure in K242328, clearance date 10/31/2024.<br><br>**Different from Predicate**<br>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, cleared 1/25/2007) | **Subject Device** PowerPort™ M.R.I. ™ Implantable Port | **Subject Device** PowerPort™ M.R.I.™ isp Implantable Port | **Discussion** |
|---|---|---|---|---|
| | | | | *The Groshong catheter maintenance protocol was cleared for Groshong catheters in K133335, clearance date 02/14/2014 |
| *Sterilization Method* | Ethylene Oxide | Ethylene Oxide | | **Same as Predicate** |
| *Shelf Life* | 1 year | **2 years** | | **Different than Predicate** 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). 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. There was no change to indications for use, warnings, precautions, |

| **Attribute** | **Predicate Device** PowerPort™ Implanted Polymeric Port (K063377, cleared 1/25/2007) | **Subject Device** PowerPort™ M.R.I. ™ Implantable Port | **Subject Device** PowerPort™ M.R.I.™ isp Implantable Port | **Discussion** |
|---|---|---|---|---|
| | | | | 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** |

## 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 PowerPort™ Implantable Ports rely on these standards of practice for their institutional protocols. The goal is to ensure that PowerPort™ 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 in K242328, clearance date 10/31/2024.

**Dimensional Changes**

The subject devices use the same materials as the predicate device, so all material evaluations for the predicate device are applicable to the subject device. Additionally, the catheters were previously qualified and cleared as part of K072549 and K072215. 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. The long white ChronoFlex (no purple colorant) polyurethane catheter has been previously used for non-power injectable ports. 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. Performance verification and validation cleared the new catheter for power-injection use and demonstrated that no new risks were introduced or modified. 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.

**Shelf-Life Changes**

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). 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.

**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. 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. 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 4: 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<br>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)<br>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)<br>ASTM D412 |
| Port System Flow Rate | BAS Internal Test-Method |

**Conclusion:**

Bard Access Systems, Inc. concludes that the subject devices, PowerPort™ isp Implantable Port, PowerPort™ Slim Implantable Port, PowerPort™ M.R.I.™ Implantable Port, and PowerPort™ M.R.I.™ isp Implantable Port, are substantially equivalent to the legally marketed predicate devices.