July 8, 2019

C.R. Bard, Inc.
Jeff Peterson
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, Utah 84116

Re: K181446
Trade/Device Name: Bard Power-Injectable Implantable Ports (PowerPorts®)
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port And Catheter
Regulatory Class: Class II
Product Code: LJT
Dated: June 5, 2019
Received: June 6, 2019

Dear Jeff Peterson:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

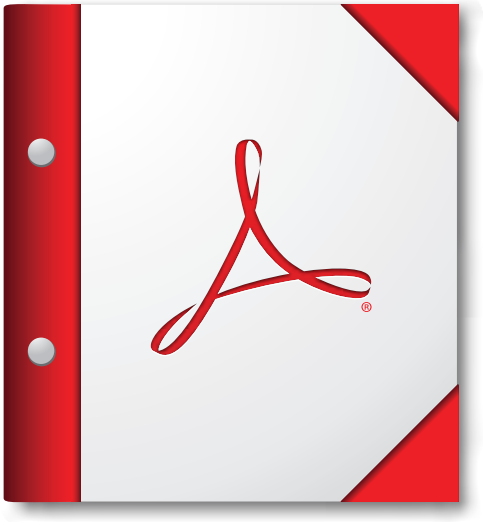
Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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,

for Nikhil Thakur
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



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**510(k) Summary (21 CFR 807.92)**
**Bard PowerPort® Implantable Ports**
**K181446**

**Submitter Information:**

Bard Access Systems (C.R. Bard, Inc.)
605 North 5600 West
Salt Lake City, Utah 84116

Phone: 480-303-2738
Fax: 480-449-2546

Contact Person: Jeff Peterson
Regulatory Affairs Specialist
Date of Submission: July 3, 2019

**Subject Device Name:**

Name of Device:

- PowerPort® ClearVUE® isp Implantable Port
- PowerPort® ClearVUE® Slim Implantable Port
- PowerPort® isp M.R.I.® Implantable Port
- PowerPort® M.R.I.® Implantable Port
- PowerPort® duo M.R.I® Implantable Port
- PowerPort® isp Implantable Port
- PowerPort® Slim Implantable Port
- PowerPort® Implantable Port
- PowerPort® VUE Implantable Port
- PowerPort® Vue M.R.I.® Implantable Port
- Vaccess CT Power-Injectable Port
- Vaccess CT Low-Profile Titanium Power-Injectable Port

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|---|---|
| Common or Usual Name: | Implanted Infusion Port |
| Product Code: | LJT – Port & Catheter, Implanted, Subcutaneous, Intravascular |
| Regulation Name: | Subcutaneous, implanted intravascular infusion port and catheter |
| Regulatory Class: | Class 2 |
| Regulation Number: | 21 CFR §880.5965 |

**Predicate Device:**

Name of Device:

- PowerPort® Implanted Titanium Port with 8 Fr. Chronoflex® Polyurethane Catheter (K060812)
- PowerPort® Implanted Polymeric Port with 8

Fr. Chronoflex® Catheter (K063377)

- Titanium PowerPort® isp Implanted Port with 8 Fr. Chronoflex® Polyurethane Catheter (K072215)
- Titanium PowerPort® isp Implanted Port with 6 Fr. Chronoflex® Polyurethane Catheter (K072549)
- MRI PowerPort® Implanted Port with 9.6 Fr Silicone Catheter (K073423)
- PowerPort® Implanted Port with Groshong® Catheter (K081311)
- PowerPort® duo M.R.I. ® Implanted Port with 9.5 Fr. Dual Lumen Chronoflex® Polyurethane Catheter (K090512)
- PowerPort® ClearVUE® Slim Implantable Port with 8Fr. Polyurethane Catheter (K122899)

| | |
|---|---|
| Common or Usual Name: | Implanted Infusion Port |
| Product Code: | LJT – Port & Catheter, Implanted, Subcutaneous, Intravascular |
| Regulation Name: | Subcutaneous, implanted intravascular infusion port and catheter |
| Regulatory Class: | Class 2 |
| Regulation Number: | 21 CFR §880.5965 |

**Summary of Change:**

The purpose of the bundled submission is to expand the indications for use for this family of ports. The Indications for Use statements are being expanded to include the clarifying statement "including anti-cancer medicines (chemotherapy)" as related to the infusion of medicines.

**Device Descriptions:**

PowerPort® Implantable Ports are designed to provide repeated access to the vascular system without the need for repeated venipuncture or daily care of an external catheter. Implantable Ports consist of a rigid housing and a self-sealing septum. The catheters used with infusion ports are essentially the same design as externalized, stand-alone intravascular catheters. Catheters, included with the port, are pre-attached or may be attached to the port by the physician during implantation.

PowerPort® Implantable Ports can be used for routine vascular access using a non-coring access needle. However, for power injection procedures, PowerPort® ports must be accessed with a Bard PowerLoc® Safety Infusion Set (SIS) to create a power-injectable system.

**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 a 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.

**Technological Comparison to Predicate Devices:**

There have been no changes to the technological characteristics or design including the device's physical attributes or manufacturing specifications of the Bard Power-Injectable Implantable Ports; therefore, they are identical and substantially equivalent with respect to basic design and function of the predicate devices. Expanding the indications for use statement to include the clarifying statement "including anti-cancer medicines (chemotherapy)" as related to the infusion of medicines, does not impact the intended use, and does not raise any new questions regarding safety or efficacy. The subject devices and the predicate devices are identical in the following ways:

- Same Intended Use
- Same Target Population
- Same Technological Characteristics
- Same Fundamental Scientific Technology
- Same Operating Principle
- Same Implant Design and Materials
- Same Applicator Design and Materials
- Same Performance Specifications
- Same Packaging Materials and Configurations
- Same Sterility Assurance Level and Method of Sterilization

The subject devices and the predicate devices are different in the following manner only:

- Expanded Indications for Use

There are no other changes to subject devices, see Table below.

## Subject and Predicate Device Comparison

| | Subject Devices | Predicate Devices |
|---|---|---|
| **Legal Manufacturer** | No change from predicates | Bard Access Systems, Inc. |
| **510(k) Status** | PowerPort® ClearVUE® isp Implantable Port | PowerPort® Implanted Polymeric Port with 8 Fr. Chronoflex® Catheter (K063377) |
| | PowerPort® ClearVUE® Slim Implantable Port | PowerPort® ClearVUE® Slim Implantable Port with 8Fr. Polyurethane Catheter (K122899) |
| | PowerPort® isp M.R.I.® Implantable Port | MRI PowerPort® Implanted Port with 9.6 Fr Silicone Catheter (K073423)<br>PowerPort® Implanted Polymeric Port with 8 Fr. Chronoflex® Catheter (K063377) |
| | PowerPort® M.R.I.® Implantable Port | MRI PowerPort® Implanted Port with 9.6 Fr Silicone Catheter (K073423)<br>PowerPort® Implanted Polymeric Port with 8 Fr. Chronoflex® Catheter (K063377) |
| | PowerPort® duo M.R.I.® Implantable Port | PowerPort® duo M.R.I. ® Implanted Port with 9.5 Fr. Dual Lumen Chronoflex® Polyurethane Catheter (K090512) |
| | PowerPort® isp Implantable Port | PowerPort® Implanted Port with Groshong® Catheter (K081311)<br>Titanium PowerPort® isp Implanted Port with 6 Fr. Chronoflex® Polyurethane Catheter (K072549)<br>Titanium PowerPort® isp |

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| | | Implanted Port with 8 Fr. Chronoflex® Polyurethane Catheter (K072215) |
| | PowerPort® Slim Implantable Port | PowerPort® Implanted Port with Groshong® Catheter (K081311)<br>Titanium PowerPort® isp Implanted Port with 6 Fr. Chronoflex® Polyurethane Catheter (K072549)<br>Titanium PowerPort® isp Implanted Port with 8 Fr. Chronoflex® Polyurethane Catheter (K072215) |
| | PowerPort® Implantable Port | PowerPort® Implanted Port with Groshong® Catheter (K081311)<br>MRI PowerPort® Implanted Port with 9.6 Fr Silicone Catheter (K073423)<br>PowerPort® Implanted Titanium Port with 8 Fr. Chronoflex® Polyurethane Catheter (K060812) |
| | PowerPort® VUE Implantable Port | Titanium PowerPort® isp Implanted Port with 6 Fr. Chronoflex® Polyurethane Catheter (K072549) |
| | PowerPort® Vue M.R.I.® Implantable Port | PowerPort® Implanted Polymeric Port with 8 Fr. Chronoflex® Catheter (K063377) |
| | Vaccess CT Power-Injectable Port | PowerPort® Implanted Polymeric Port with 8 Fr. Chronoflex® Catheter (K063377)<br>Titanium PowerPort® isp Implanted Port with 6 Fr. |

| | | |
|---|---|---|
| | | Chronoflex® Polyurethane Catheter (K072549) |
| | Vaccess CT Low-Profile Titanium Power-Injectable Port | Titanium PowerPort® isp Implanted Port with 6 Fr. Chronoflex® Polyurethane Catheter (K072549)<br>Titanium PowerPort® isp Implanted Port with 8 Fr. Chronoflex® Polyurethane Catheter (K072215) |
| **Intended Use** | No change from predicates | PowerPort® Implantable Ports are intended to be an implanted vascular access device designed to provide long-term, repeated access to the vascular system. |
| **Indications for Use** | 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.<br><br>When used with a PowerLoc® Brand 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. | K063377:<br><br>The PowerPort® Implanted Port is indicated for patient vascular therapies requiring repeated access to vascular the 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.<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. |

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| | | K060812, K072215, K072549, K073423, K090512, K081311: 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 medication, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.<br><br>When used with a PowerLocTM safety infusion set, the PowerPortTM device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.<br><br>K122899:<br><br>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.<br><br>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 |

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| | | infusion rate is 5 ml/s. |
| **Technological Characteristics** | No change from predicates | Ports are implanted subcutaneously for long-term repeatable vascular access.<br>PowerPorts® are unique in that they can also be power injected with contract media for CT imaging. |
| **Features** | No change from predicates | Port Body (including a self-sealing silicone septum),<br>Radiopaque Catheter,<br>CathLock |
| **Materials** | No change from predicates | Various Materials |
| **Principles of Operation** | No change from predicates | Implantable access device designed to provide repeated access to the vascular system. |
| **Sterilization** | No change from predicates | Sterilized to a minimum SAL level of $1 \times 10^{-6}$ |
| **Shelf Life** | No change from predicates | Shelf life for these devices was established by evaluating the physical performance of the ports and catheters with test components either accelerated aged or real time aged to 2 years. |
| **Packaging** | No change from predicates | These devices are packaged in three kit configurations: Basic, Intermediate, and Microintroducer. |

**Note**: Device Indications for Use in **Bold** indicates a difference between the subject devices and predicate device.

The subject device labeling has been revised/updated to include the expanded Indications for Use language regarding a clarifying statement of “including anti-cancer medicines (chemotherapy)” as related to the infusion of medicines.

**Performance Data:**

Verification and validation activities were designed and performed in accordance with Design Controls as per 21 CFR §820.30. The following guidance documents in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device:

- FDA Guidance on 510(k) Submissions for Implanted Infusion Ports, October 1990
- FDA Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, March 16, 1995

Based upon the evaluation of the methods provided in the guidance, the following verification tests were conducted as Performance Testing – Bench:

- Stem-Catheter Air Leak Test
- Stem-Catheter Air Burst Test
- Stem-Catheter Tensile Strength Test
- Multiple Power Injections Test
- Port System Injection Rate Test

During performance testing, the devices underwent chemical conditioning which consisted of exposing the port, catheter, and CathLock junctions to chemicals simulating those used during chemotherapy infusions in the clinical environment. The testing also demonstrated that devices were able to further withstand and pass all of the robust physical testing sited above and have met all of the essential requirements identified.

The subject device met all pre-determined acceptance criteria and demonstrated substantial equivalence as compared to the predicate device.

**Clinical Analysis:**

The expanded indications for use to include clarifying statement “including anti-cancer medicines (chemotherapy)” as related to the infusion of medicines is clinically supported by a comprehensive literature review. The review assessed relevant clinical literature related to the use of ports for the administration of chemotherapy medications for patients with cancer diagnoses. To further reinforce the use of ports for administering chemotherapy medications, Bard analyzed real-world evidence and sponsored retrospective studies. This data, summarized below, demonstrates the use of ports for administering chemotherapy medications for patients diagnosed with cancer.

A comprehensive literature review was conducted to collect and assess relevant clinical literature documenting the use of totally implantable ports for chemotherapy infusion in cancer patients. The literature reviewed encompassed two randomized controlled trials, four

prospective registries, and five retrospective analyses. Bard® ports were used in all reviewed studies and showed the widespread use of implanted ports for chemotherapy.

A retrospective analysis of US health care claims data was conducted to assess the diagnosis codes related to procedures for the insertion of tunneled centrally inserted venous access devices with subcutaneous ports. The results revealed that 92% of procedures were related to a type of Cancer.

Two separate retrospective studies[1,2] demonstrated that ports are primarily used for the administration of chemotherapy for oncology patients with cancer diagnoses. Please see the summaries below:

One study[1] was a multicenter, retrospective data review to evaluate the maintenance flushing interval for patients using the Groshong® Distal Valved Port Catheter from C. R. Bard. Patient data was collected from five different clinical sites for patients who were at least 21 years of age, had a Bard® Groshong® Port Catheter, had completed cancer therapy, and had maintenance flushes with heparin/heparinized saline or normal saline.

The second study[2] was a multicenter, retrospective database review to determine the adverse event (AE)/malfunction rates of ports and PIVs in subjects undergoing chemotherapy infusions. The purpose of the study was to collect data on subjects receiving chemotherapy to determine complication rates with ports and PIVs. Study subjects consisted of adult males and females ≥21 years of age who had infusions through a Bard port or any PIV.

These studies are included solely to demonstrate that ports are primarily used for the administration of chemotherapy (chemotherapy infusions) for oncology patients with cancer diagnoses.

**Summary of Substantial Equivalence:**

Based on the indications for use, technological characteristics, and additional performance testing, the Bard Power-Injectable Implantable Ports (PowerPorts®) meet the requirements that are considered sufficient for their intended use, and are substantially equivalent in design, materials, sterilization, and principles of operation to the legally marketed predicate devices cited.

References

[1] McDonald M. *Veins For Life Study*: A retrospective multicentered study to assess the complication rates of oncology patients accessed with peripheral intravenous lines versu implantable ports for chemotherapy administration. 2017. Funded by C.R. Bard, Inc.

[2] DiMatteo C, Nishimoto B, Thomas I. *Distal Study*: A retrospective study to extend the maximum maintenance flushing interval for ports with distally valved catheters. 2014. Funded by C.R. Bard, Inc.