November 20, 2015

C.R. Bard, Inc.
Mr. James Davis
Regulatory Affairs Specialist
Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, Utah 84116

Re: K150514
Trade/Device Name: Power-injectable Implantable Ports with Chronoflex® Polyurethane Catheters
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: October 22, 2015
Received: October 23, 2015

Dear Mr. Davis:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
**Indications for Use**

**Device Name**
Power-Injectable Implantable Ports with ChronoFlex® Polyurethane Catheters

**Indications for Use (Describe)**
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 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.

**Type of Use (Select one or both, as applicable)**

- [ ] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

*CONTINUE ON A SEPARATE PAGE IF NEEDED.*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

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- Food and Drug Administration
- Office of Chief Information Officer
- Paperwork Reduction Act (PRA) Staff
- PRAS Staff@fda.hhs.gov

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.*
### 510(k) Summary

#### 21 CFR 807.92

**Power-Injectable Implantable Ports with ChronoFlex® Polyurethane Catheters**

<table>
<thead>
<tr>
<th>General Provisions</th>
</tr>
</thead>
</table>
| **Submitter Name:** Bard Access Systems, Inc.  
**Address:**  
605 North 5600 West  
Salt Lake City, UT 84116 | |
| **Contact Person:** James R. Davis  
Regulatory Affairs Specialist  
James.R.Davis@crbard.com  
801.522.5000 ext 5456  
801.522.5425 | |
| **Date of Preparation:** 22 October 2015 | |

<table>
<thead>
<tr>
<th>Subject Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trade Name:</strong> Power-Injectable Implantable Ports with ChronoFlex® Polyurethane Catheters</td>
</tr>
<tr>
<td><strong>Common/Usual Name:</strong> Implanted Infusion Port &amp; Catheter</td>
</tr>
<tr>
<td><strong>Classification Name:</strong> Subcutaneous, Implanted, Intravascular Infusion Port and Catheter</td>
</tr>
</tbody>
</table>
| **Product Code:** LJT  
**Regulation:** 21 CFR 880.5965 |

<table>
<thead>
<tr>
<th>Predicate Device</th>
</tr>
</thead>
</table>
| **Trade Name:** PowerPort® ClearVUE® Slim Implantable Port  
**Classification Name:** Subcutaneous, Implanted, Intravascular Infusion Port and Catheter |
| **Premarket Notification:** K122899  
**Manufacturer:** Bard Access Systems, Inc. |

<table>
<thead>
<tr>
<th>Reference Devices</th>
</tr>
</thead>
</table>
| **Trade Name:** Titanium PowerPort® ISP Implantable Port with 6 Fr. ChronoFlex® Polyurethane Catheter  
**Classification Name:** Subcutaneous, Implanted, Intravascular Infusion Port and Catheter |
| **Premarket Notification:** K072549  
**Manufacturer:** Bard Access Systems, Inc. |
| **Trade Name:** PowerPort® Polymeric Port with 8 F S/L ChronoFlex® Catheters  
**Classification Name:** Subcutaneous, Implanted, Intravascular Infusion Port and Catheter |
| **Premarket Notification:** K063377  
**Manufacturer:** Bard Access Systems, Inc. |
Reference Devices Justification

The references devices are provided because a bundled 510(k) submission is appropriate for the subject device since the scientific and regulatory issues are most efficiently addressed during one review. Additionally, the performance data is the same for the subject devices, only the General Hospital review branch is involved with the review process and the devices have the same indications for use.

Subject and Predicate Device Comparison

<table>
<thead>
<tr>
<th>Attribute</th>
<th>SUBJECT DEVICE</th>
<th>PREDICATE DEVICE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Power-Injectable Implantable Ports with ChronoFlex Polyurethane Catheters</td>
<td>PowerPort® ClearVUE® Slim Implantable Port (K122899)</td>
</tr>
<tr>
<td><strong>Note</strong></td>
<td>● <strong>Bold red font</strong> indicates a difference between the subject device and the current regulatory predicate baseline of the predicate device.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>● Plain type indicates that the attribute of the subject device is the same as that of the current regulatory baseline of the predicate device.</td>
<td></td>
</tr>
<tr>
<td>Owner</td>
<td>Same</td>
<td>Bard Access Systems, Inc.</td>
</tr>
<tr>
<td>510(k) Status</td>
<td>Subject of this Premarket Notification</td>
<td>K122899</td>
</tr>
<tr>
<td></td>
<td>Concurrence Date: November 15th, 2012</td>
<td></td>
</tr>
<tr>
<td>Classification</td>
<td>Same</td>
<td>21 CFR 880.5965 – Class II</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LJT – Subcutaneous, implanted, intravascular infusion port and catheter</td>
</tr>
<tr>
<td>Intended Use</td>
<td>Same</td>
<td>Power-Injectable Implantable Ports are intended to be an implanted vascular access device designed to provide long-term, repeated access to the vascular system.</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td></td>
<td>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 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.</td>
<td></td>
</tr>
<tr>
<td>Duration of Use</td>
<td>Same</td>
<td>Long term (&gt;30 days)</td>
</tr>
<tr>
<td>Insertion Site</td>
<td>Same</td>
<td>Port is implanted subcutaneously with catheter tunneled and inserted in blood vessel</td>
</tr>
<tr>
<td>Catheter Tip Location</td>
<td>Same</td>
<td>Central venous system – lower 1/3 of superior vena cava preferred</td>
</tr>
<tr>
<td>Significant Device Dimensions</td>
<td>8 Fr. &amp; 6 Fr. Catheter Surface Profilometry RMS Value: ≤0.5µm</td>
<td>8 Fr. &amp; 6 Fr. Catheter Surface Profilometry N/A</td>
</tr>
<tr>
<td>Catheter Body Materials</td>
<td>Same</td>
<td>Polyurethane</td>
</tr>
<tr>
<td>Port Body Materials</td>
<td>Same</td>
<td>Polyetheretherketone (Body/Stem) Silicon (Suture Plugs)</td>
</tr>
<tr>
<td>Catheter Lock Materials</td>
<td>Same</td>
<td>Polycarbonate</td>
</tr>
<tr>
<td>Device Description</td>
<td>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. Long-Term 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. Polyurethane catheters are 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. The ChronoFlex® Polyurethane Catheters maintain an average root mean square catheter surface profilometry of less than 0.5µm.</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Technological Characteristics</td>
<td>The technological characteristics of the subject Power-Injectable Ports with ChronoFlex® Polyurethane Catheters are substantially equivalent with respect to design and function to those of the predicate devices.</td>
<td></td>
</tr>
</tbody>
</table>
Verification and validation activities were designed and performed in accordance with Design Controls as per 21 CFR §820.30. The following guidance documents and standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device:

- FDA Guidance – Guidance on 510(k) Submissions for Implanted Infusion Ports; October, 1990
- FDA Guidance – General Considerations for Animal Studies for Cardiovascular Devices, dated July 29, 2010
- FDA Guidance – Bundling Multiple Devices or Multiple Indications in a single submission, dated June 22, 2007
- FDA Guidance – Establishing safety and compatibility of passive implants in the magnetic resonance environment, dated August 21, 2008
- ISO 10993-7 Second Edition 2008-10-15, Biological Evaluation for Medical Devices; Part 7 – Ethylene Oxide Sterilization Residuals

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

Performance Tests

Testing Conclusion

The results of the testing performed demonstrate the subject device performance is substantially equivalent to the predicate device.

Summary of Substantial Equivalence

Based on the indications for use, technological characteristics, and performance testing, the subject Power-Injectable Ports with ChronoFlex® Polyurethane Catheters meets the requirements that are considered sufficient for its intended use and demonstrates that the subject devices are substantially equivalent to the predicate devices cited.