DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 20, 2016

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

Re: K153359
Trade/Device Name: BardPort®, SlimPort®, and X-Port® Implanted Ports
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: April 21, 2016
Received: April 22, 2016

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,

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

510(k) Number (if known): K153359

Device Name: BardPort®, SlimPort®, and X-Port® Implanted Ports

Indications for Use:

The BardPort®, SlimPort®, and X-Port® implanted ports are 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.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
21 CFR 807.92

BardPort®, SlimPort®, and X-Port® Implanted Ports

General Provisions	Submitter Name: Address:	Bard Access Systems, Inc. 605 North 5600 West Salt Lake City, UT 84116
	Contact Person	James R. Davis Regulatory Affairs Specialist James.R.Davis@crbard.com T: 801.522.5456 F: 801.522.5425
	Date of Preparation:	February 5th, 2016
Subject Device	Trade Name: Common/Usual Name: Classification Name: Product Code: Regulation:	BardPort®, SlimPort®, and X-Port® Implanted Ports Implanted Infusion Port & Catheter Subcutaneous, Implanted, Intravascular Infusion Port and Catheter LJT 21 CFR 880.5965
Predicate Devices	Current Trade Name: Classification Name: Premarket Notification: Manufacturer:	X-Port® Implanted Ports Subcutaneous, Implanted, Intravascular Infusion Port and Catheter K022983: BardPort® X-Port® *isp* Port Bard Access Systems, Inc.
	Current Trade Name: Classification Name: Premarket Notification: Manufacturer:	BardPort® and SlimPort® Implanted Ports Subcutaneous, Implanted, Intravascular Infusion Port and Catheter K924250: Plastic Low Profile Subcutaneous Port Bard Access Systems, Inc.
	Current Trade Name: Classification Name: Premarket Notification: Manufacturer:	BardPort® Implanted Ports Subcutaneous, Implanted, Intravascular Infusion Port and Catheter K880571: Cath-Tech Port Implantable Vascular Access System Bard Access Systems, Inc.

Predicate Devices (continued)	Current Trade Name: Classification Name: Premarket Notification: Manufacturer:	BardPort® Implanted Ports Subcutaneous, Implanted, Intravascular Infusion Port and Catheter K873213: Hickman Plastic Subcutaneous Port Bard Access Systems, Inc.
	Current Trade Name: Classification Name: Premarket Notification: Manufacturer:	BardPort® Implanted Ports Subcutaneous, Implanted, Intravascular Infusion Port and Catheter K870260: Hickman Titanium Subcutaneous Port Bard Access Systems, Inc.
Bundled 510(k) Submission Justification	Multiple Predicate Devices are provided because a Bundled 510(k) Submission is appropriate for the subject devices since the scientific and regulatory issues are most efficiently addressed during one review. The same changes are being performed to all of the Predicate Device baselines. Additionally, following the criteria given within the Bundled 510(k) FDA Guidance: the performance data is the same for the subject devices, the General Hospital review branch is the only branch involved with the review process and all of the Predicate Devices have the same indications for use.	
Reference Device	Current Trade Name: Classification Name: Premarket Notification: Manufacturer:	PowerPort® Implanted Ports with Groshong® Catheter Subcutaneous, Implanted, Intravascular Infusion Port and Catheter K081311: PowerPort® Implanted Ports with Groshong® Catheter Bard Access Systems, Inc.
Reference Devices Justification	The references device is provided because the exact same changes in dimensions to the Port-Catheter Stem and Catheter Lock as well as the exact same Groshong® Catheter formulation change and Catheter Lock radiopaque material were cleared within the K081311 clearance. These exact same design features cleared in K081311 are being adapted to the BardPort®, SlimPort®, and X-Port® Implanted Ports.	
Device Description	BardPort®, SlimPort®, and X-Port® Implanted Ports are designed to provide repeated access to the vascular system without the need for repeated venipuncture or daily care of an external catheter. BardPort®, SlimPort®, and X-Port® Implanted 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. Groshong® catheters are attached to the port by the physician during implantation. BardPort®, SlimPort®, and X-Port® Implanted Ports can be used for routine vascular access using a non-coring access needle.	
Intended Use	BardPort®, SlimPort®, and X-Port® Implanted 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 BardPort®, SlimPort®, and X-Port® Implantable Ports are 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.
Technological Characteristics	Technological characteristics of the subject BardPort®, SlimPort®, and X-Port® Implantable Ports are substantially equivalent with respect to basic design and function to those of the predicate devices. The Port-Catheter Stem and Catheter Lock design changes have different dimensions in comparison to the predicate device. Additionally, the Groshong® Catheter formulation is different from the predicate device to make a solid blue extrusion and the Catheter Lock radiopaque material is different so that the radiopaque band can be printed onto the subject Catheter Lock. The differences are not critical to the intended use of the device.

Subject and Predicate Device Comparison (K022983)

Attribute	SUBJECT DEVICE X-Port® Implanted Ports	PREDICATE DEVICE BardPort® X-Port® *isp* Port
Note	**Bold red font:** Difference between the subject device and the current regulatory baseline of the predicate device. Normal font: No difference between the subject device and the current regulatory baseline of the predicate device.	
Owner	Same	Bard Access Systems, Inc.
510(k) Status	Subject of this Premarket Notification	**K022983** Concurrence Date: September 25, 2002
Classification	Same	21 CFR 880.5965 – Class II LJT – Subcutaneous, implanted, intravascular infusion port and catheter
Intended Use	Same	Non Power-Injectable 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	Same	The BardPort®, SlimPort®, and X-Port® Implanted Ports are 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.
Duration of Use	Same	Long term (>30 days)
Insertion Site	Same	Port is implanted subcutaneously with catheter tunneled and inserted in blood vessel
Catheter Tip Location	Same	Central venous system – lower 1/3 of superior *vena cava* preferred
Catheter Dimensions	Same	Usable Length: 45cm French Size: 8
Port Body Dimensions	Same	Reservoir Volume: 0.6 mL Septum Diameter: 12.7 mm
Port-Catheter Stem Dimensions	Total Length: **0.570”**	Total Length: 0.565”
Catheter Lock Dimensions	Total Length: **0.405”** Lock Step Ø: .100”	Total Length: 0.552” Lock Step Ø: 0.100”
Catheter Material	Silicone with a **solid** blue extrusion	Silicone with a striped blue extrusion
Port Body Material	Same	Port Base & Top: Delrin Suture Plug(s) & Septum: Silicone
Port-Catheter Stem Material	Same	Titanium
Catheter Lock Material	Polycarbonate with radiopaque **print**	Polycarbonate with radiopaque sleeve

Subject and Predicate Device Comparison (K924250)

Attribute	SUBJECT DEVICE BardPort® and SlimPort® Implanted Ports	PREDICATE DEVICE Plastic Low Profile Subcutaneous Port
Note	**Bold red font:** Difference between the subject device and the current regulatory baseline of the predicate device. Normal font: No difference between the subject device and the current regulatory baseline of the predicate device.	
Owner	Same	Bard Access Systems, Inc.
510(k) Status	Subject of this Premarket Notification	**K924250** Concurrence Date: October 4, 1993
Classification	Same	21 CFR 880.5965 – Class II LJT – Subcutaneous, implanted, intravascular infusion port and catheter
Intended Use	Same	Non Power-Injectable 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	Same	The BardPort®, SlimPort®, and X-Port® Implanted Ports are 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.
Duration of Use	Same	Long term (>30 days)
Insertion Site	Same	Port is implanted subcutaneously with catheter tunneled and inserted in blood vessel
Catheter Tip Location	Same	Central venous system – lower 1/3 of superior *vena cava* preferred
Catheter Dimensions	Same	Usable Length: 45cm French Size: 8
Port Body Dimensions	Same	Reservoir Volume: 0.3 mL Septum Diameter: 10.7 mm
Port-Catheter Stem Dimensions	Total Length: **0.570”**	Total Length: 0.565”
Catheter Lock Dimensions	Total Length: **0.405”** Lock Step ø: .100”	Total Length: 0.552” Lock Step ø: 0.100”
Catheter Material	Silicone with a **solid** blue extrusion	Silicone with a striped blue extrusion
Port Body Material	Same	Port Base & Top: Delrin Suture Plug(s) & Septum: Silicone
Port-Catheter Stem Material	Same	Titanium
Catheter Lock Material	Polycarbonate with radiopaque **print**	Polycarbonate with radiopaque sleeve

Subject and Predicate Device Comparison (K880571)

Attribute	SUBJECT DEVICE BardPort® Implanted Ports	PREDICATE DEVICE Cath-Tech Port Implantable Vascular Access System
Note	**Bold red font:** Difference between the subject device and the current regulatory baseline of the predicate device. Normal font: No difference between the subject device and the current regulatory baseline of the predicate device.	
Owner	Same	Bard Access Systems, Inc.
510(k) Status	Subject of this Premarket Notification	**K880571** Concurrence Date: September 18, 1991
Classification	Same	21 CFR 880.5965 – Class II LJT – Subcutaneous, implanted, intravascular infusion port and catheter
Intended Use	Same	Non Power-Injectable 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	Same	The BardPort®, SlimPort®, and X-Port® Implanted Ports are 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.
Duration of Use	Same	Long term (>30 days)
Insertion Site	Same	Port is implanted subcutaneously with catheter tunneled and inserted in blood vessel
Catheter Tip Location	Same	Central venous system – lower 1/3 of superior *vena cava* preferred
Catheter Dimensions	Same	Usable Length: 45cm French Size: 8
Port Body Dimensions	Same	Reservoir Volume: 0.5 mL Septum Diameter: 13.0 mm
Port-Catheter Stem Dimensions	Total Length: **0.570”**	Total Length: 0.565”
Catheter Lock Dimensions	Total Length: **0.405”** Lock Step ø: .100”	Total Length: 0.552” Lock Step ø: 0.100”
Catheter Material	Silicone with a **solid** blue extrusion	Silicone with a striped blue extrusion
Port Body Material	Same	Port Base & Top: Titanium Suture Plug(s) & Septum: Silicone
Port-Catheter Stem Material	Same	Titanium
Catheter Lock Material	Polycarbonate with radiopaque **print**	Polycarbonate with radiopaque sleeve

Subject and Predicate Device Comparison (K873213)

Attribute	SUBJECT DEVICE BardPort® Implanted Ports	PREDICATE DEVICE Hickman Plastic Subcutaneous Port
Note	**Bold red font:** Difference between the subject device and the current regulatory baseline of the predicate device. Normal font: No difference between the subject device and the current regulatory baseline of the predicate device.	
Owner	Same	Bard Access Systems, Inc.
510(k) Status	Subject of this Premarket Notification	**K873213** Concurrence Date: October 27, 1987
Classification	Same	21 CFR 880.5965 – Class II LJT – Subcutaneous, implanted, intravascular infusion port and catheter
Intended Use	Same	Non Power-Injectable 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	Same	The BardPort®, SlimPort®, and X-Port® Implanted Ports are 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.
Duration of Use	Same	Long term (>30 days)
Insertion Site	Same	Port is implanted subcutaneously with catheter tunneled and inserted in blood vessel
Catheter Tip Location	Same	Central venous system – lower 1/3 of superior *vena cava* preferred
Catheter Dimensions	Same	Usable Length: 45cm French Size: 8
Port Body Dimensions	Same	Reservoir Volume: 0.6 mL Septum Diameter: 12.5 mm
Port-Catheter Stem Dimensions	Total Length: **0.570”**	Total Length: 0.565”
Catheter Lock Dimensions	Total Length: **0.405”** Lock Step ø: .100”	Total Length: 0.552” Lock Step ø: 0.100”
Catheter Material	Silicone with a **solid** blue extrusion	Silicone with a striped blue extrusion
Port Body Material	Same	Port Base & Top: Delrin Suture Plug(s) & Septum: Silicone
Port-Catheter Stem Material	Same	Titanium
Catheter Lock Material	Polycarbonate with radiopaque **print**	Polycarbonate with radiopaque sleeve

Subject and Predicate Device Comparison (K870260)

Attribute	SUBJECT DEVICE BardPort® Implanted Ports	PREDICATE DEVICE Hickman Titanium Subcutaneous Port
Note	**Bold red font:** Difference between the subject device and the current regulatory baseline of the predicate device. Normal font: No difference between the subject device and the current regulatory baseline of the predicate device.	
Owner	Same	Bard Access Systems, Inc.
510(k) Status	Subject of this Premarket Notification	**K870260** Concurrence Date: April 15, 1987
Classification	Same	21 CFR 880.5965 – Class II LJT – Subcutaneous, implanted, intravascular infusion port and catheter
Intended Use	Same	Non Power-Injectable 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	Same	The BardPort®, SlimPort®, and X-Port® Implanted Ports are 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.
Duration of Use	Same	Long term (>30 days)
Insertion Site	Same	Port is implanted subcutaneously with catheter tunneled and inserted in blood vessel
Catheter Tip Location	Same	Central venous system – lower 1/3 of superior *vena cava* preferred
Catheter Dimensions	Same	Usable Length: 45cm French Size: 8
Port Body Dimensions	Same	Reservoir Volume: 0.6 mL Septum Diameter: 12.7 mm
Port-Catheter Stem Dimensions	Total Length: **0.570”**	Total Length: 0.565”
Catheter Lock Dimensions	Total Length: **0.405”** Lock Step ø: .100”	Total Length: 0.552” Lock Step ø: 0.100”
Catheter Material	Silicone with a **solid** blue extrusion	Silicone with a striped blue extrusion
Port Body Material	Same	Port Base & Top: Titanium Suture Plug(s) & Septum: Silicone
Port-Catheter Stem Material	Same	Titanium
Catheter Lock Material	Polycarbonate with radiopaque **print**	Polycarbonate with radiopaque sleeve

Performance Tests

Verification and validation activities were designed and performed in accordance with design controls (per 21 CFR §820.30) and risk analysis (per ISO 14971:2009). A declaration of conformity to design controls is located within the 510(k).

The risk analysis method utilized to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA) per the applicable in-house procedures. The risk analysis activities did not identify any new types of safety or efficacy questions for the subject BardPort®, SlimPort®, and X-Port® Implantable Ports. The risk analysis activities performed was conducted as appropriate based upon the following guidance documents and standards in conjunction with in-house protocols for evaluating the performance of the device to mitigate the risks identified:

- FDA Guidance – *Guidance on 510(k) Submissions for Implanted Infusion Ports;* October, 1990
- FDA Guidance – *Guidance on 510(k) Submissions for Short-Term and Long-Term Intravascular Catheters,* March 16, 1990
- 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 10555-1 Second Edition 2013-07-01, Sterile, Single-Use Intravascular Catheters, Part 1: General Requirements
- ISO 10555-3 Second Edition 2013-06-15, *Sterile, Single-Use Intravascular Catheters, Part 3: Central Venous Catheters*
- AAMI/ANSI/ISO 11135-1: 2007, *Sterilization of Healthcare Products – Ethylene Oxide*
- AAMI/ANSI/ISO 10993-1:2009/(R) 2013, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*, and the FDA Modified ISO 10993 Test Profile
- ISO 10993-7 Second Edition 2008-10-15, *Biological Evaluation for Medical Devices; Part 7 – Ethylene Oxide Sterilization Residuals*
- AAMI/ANSI/ISO 11607:2006/(R)2010, *Packaging for Terminally Sterilized Medical Devices*
- AAMI / ANSI ST72:2011: *Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing*
- ASTM F2503-13 (2014), *Standard Practice for marketing Medical Devices and Other Items for Safety in the Magnetic Resonance (MR) Environment*
- *Design Control Guidance for Medical Device Manufacturers, March 11, 1997*

Performance Tests (continued)	As a result of the risk analysis activities, the following verification tests were conducted: • Stem-Catheter Connection Leak Test • Stem-Catheter Connection Tensile Test • Stem-Catheter Connection Burst Test • Connection Assembly Damage Test • Connection Assembly Damage Tensile Test • Groshong® Catheter Valve Crack Pressure • Tensile Strength of Catheter Body • Catheter Stiffness • Catheter Elongation • Catheter Burst Pressure • Catheter Collapse • Catheter Priming Volume • Groshong® Catheter Tip Tensile Test • Tunneler Connection Test • Catheter Radiopacity • Catheter Fluid Leak • Catheter Air Leak
Testing Conclusion	The results of the testing performed demonstrates that the subject devices performance is substantially equivalent to the predicate devices and the risk identified as a result of the risk analysis activities were properly mitigated.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and actions taken as a result of the risk analysis activities, the BardPort®, SlimPort®, and X-Port® Implantable Ports meets the requirements that are considered sufficient for its intended use and demonstrates that the subject devices are substantially equivalent to the predicate device baselines cited.