K 122899

BARD
ACCESS SYSTEMS

NOV 15 2012

510(k) Summary
21 CFR 807.92(a)

General Provisions	Submitter Name: Address:	Bard Access Systems, Inc. 605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Amy J. Honey Regulatory Affairs Specialist
	Telephone Number:	(801) 522-5671
	Fax Number:	(801) 522-5425
	Date of Preparation:	September 19, 2012
Subject Device	Trade Name:	PowerPort® ClearVUE® Slim Implantable Port with 8F Polyurethane Catheter
	Common Name:	Implanted Infusion Port & Catheter
	Classification Name:	LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
	Product Code/ Regulation:	LJT/21 CFR §880.5965
Predicate Device	Trade Name:	Titanium PowerPort® *isp* with 8F Polyurethane Catheter
	Common Name:	Implanted Infusion Port & Catheter
	Classification Name:	LJT – Subcutaneous, Implanted, Intravascular Infusion Port & Catheter
	Product Code/ Regulation:	LJT/21 CFR §880.5965
Device Description	The PowerPort® ClearVUE® Slim with 8F Polyurethane Catheter is a member of the PowerPort® series of power-injectable implanted ports. The subject device consists of a hard plastic port and 8F polyurethane catheter that is attached to the port with a catheter lock compression fitting. The subject device is distinguishable as a member of BAS's power-injectable port series by the triangular body shape and three palpation bumps on the septum. PowerPort® implanted 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.	

Intended Use	The PowerPort® ClearVUE® Slim Implantable Port with 8F Polyurethane Catheter is intended to be an implanted vascular access device designed to provide long-term, repeated access to the vascular system.
Indications For Use	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. 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 infusion rate is 5 mL/s.
Technological Characteristics	Technological characteristics of the PowerPort® ClearVUE® Slim Implantable Port with 8F Polyurethane Catheter are substantially equivalent with respect to basic design and function of the Titanium PowerPort® *isp* with 8F Polyurethane Catheter. The differences between the two devices do not impact the intended use, and do not raise any new questions regarding safety or efficacy.
Safety & Performance Tests	Verification testing has been performed in accordance with Design Controls 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: • *Guidance on 510(k) Submissions for Implanted Infusion Ports;* October, 1990 • *Guidance – Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment;* August 21, 2008 • ASTM F2503: 2008, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance (MR) Environment* • ASTM F 2052: 2006, *Standard Test Methods for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment* • ASTM F2119: 2007, *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants* • ASTM F2182 Rev A: 2011, *Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging* • ASTM F2213: 2006 (R2011),*Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment* • ISO 10555-1/Amd 1/ Amd 2: 1195/1999/2009, *Sterile, Single-Use Intravascular Catheters, Part 1: General Requirements* • BS/EN/ISO 10555-3: 1996 Cor 1:2002, *Sterile, Single-Use Intravascular*

Catheters, Part 3: Central Venous Catheters

- AAMI/ANSI/ISO 11135-1: 2007, *Sterilization of Healthcare Products – Ethylene Oxide – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices*
- AAMI/ANSI/ISO 10993-1/Cor 1: 2009/2010, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*, and the FDA Modified ISO 10993 Test Profile
- AAMI/ANSI/ISO 10993-7:2008, *Biological Evaluation for Medical Devices; Part 7 – Ethylene Oxide Sterilization Residuals*
- USP<161>: Sept. 8, 2009, Transfusion and Infusion Assemblies and Similar Medical Devices
- AAMI ST72, Jan. 1, 2001 (R 2010): Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing

The subject device met all predetermined acceptance criteria derived from the above listed references and demonstrated substantially equivalent performance as compared to the cited predicate device.

Risk management, including a failure modes and effects analysis (FMEA) of the subject device, was conducted in accordance with ISO 14971: 2009, Medical Devices – Risk Management for Medical Devices.

Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject PowerPort ClearVUE® Slim Implantable Port with 8F Polyurethane Catheter meets the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, materials, sterilization, principles of operation, and indications for use to the predicate device cited.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 15, 2012

C.R. Bard, Incorporated
Ms. Amy Honey
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, Utah 84116

Re: K122899
Trade/Device Name: PowerPort® ClearVUE® Slim Implantable Port with 8F Polyurethane Catheter
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: September 19, 2012
Received: September 21, 2012

Dear Ms. Honey:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anthony D. Watson, 0.9.2342.19200300.100.1.1=1300092402
Date: 2012.11.15 14:01:44 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
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): K122899

Device Name: PowerPort® ClearVUE® Slim Implantable Port with 8F Polyurethane Catheter

Indications for Use:

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. 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 infusion rate is 5 mL/s.

Prescription Use ✓ (Part 21 CFR §801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Sajjad H. Syed

Digitally signed by Sajjad H. Syed
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sajjad H. Syed, 0.9.2342.19200300.100.1.1=2000601742
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122899