Section 5

PowerPort™ Implanted Polymeric Port with 8 Fr ChronoFlex® Catheter
510(k) Summary of Safety and Effectiveness
21 CFR 807.92(a)

JAN 25 2007

5.1 General Information

Submitter Name:	Bard Access Systems, Inc. (BAS) [Wholly owned Subsidiary of C.R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700 ext. 5541
Fax Number:	(801) 595-5425
Contact Person:	Michaela Rivkowich
Date of Preparation:	November 6, 2006
Registration Number:	1720496
Additional Registration Numbers:	
C.R. Bard	2212754

5.2 Subject Device Information

Device Name:	PowerPort™ Implanted Polymeric Port with 8 Fr ChronoFlex® Catheter
Trade Name:	PowerPort™, ChronoFlex®
Common/Usual Name:	Implanted Infusion Port and Catheter
Classification Name:	Class II, 80 LJT Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Classification Panel:	General Hospital

5.3 Predicate Device Information

Device Name:	PowerPort™ Implanted Titanium Port with 8 Fr ChronoFlex® Catheter
Trade Name:	PowerPort™, ChronoFlex®
Common/Usual Name:	Implanted Infusion Port and Catheter
Classification Name:	Class II, 80 LJT Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Classification Panel:	General Hospital

5.4 Intended Use

The intended use is the same as for the predicate device.

The PowerPort™ Polymeric Port is a totally implantable vascular access device designed to provide long-term, repeated access to the vascular system.

5.5 Indications for Use

The indications for use are the same as those for the predicate device.

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 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.

5.6 Device Description

The PowerPort™ device consists of a plastic port and an 8 Fr open-ended single lumen ChronoFlex® catheter which is attached to the port with a cathlock. The port is triangular in shape and has three palpation bumps to distinguish it as power injectable. Purple colorants have been added to the port and catheter materials to provide the device with an appearance that allows the placing physician to identify the PowerPort device as power injectable.

5.7 Technological Comparison to Predicate Device

The technological characteristics of the PowerPort™ Polymeric Port and 8 Fr ChronoFlex® Catheter are substantially equivalent to those of the predicate PowerPort™ Titanium Port and 8 Fr ChronoFlex® Catheter in terms of intended use, indications for use, application, user population, basic design, performance and labeling.

5.8 510(k) Substantial Equivalence Decision Tree

New device is compared to Marketed Device?

- Yes. PowerPort™ Polymeric Port device is compared to the predicate PowerPort™ Titanium Port device.

Does the new device have the same indication statement and the same intended use as the predicate device?

- Yes. The intended use and the indications for use are the same as those for the predicate device.

Does the new device have the same technological characteristics, e.g. design, material, etc?

- No, not in all regards. The PowerPort™ Polymeric Port has some minor differences from the predicate PowerPort™ Titanium Port; however, the fundamental scientific technology of the device has not changed.

Could the new characteristics affect safety or effectiveness?

- Yes. The design changes may affect safety or effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions?

- No. There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics?

- Yes. Testing was based on FDA guidance documents and recognized standards to evaluate the device's performance:

  - *Guidance on 510(k) Submissions for Implanted Infusion Ports, dated October 1990*
  - *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, dated 3/16/95*

- *BS/EN/ISO 10555-1: 1997, Sterile, single-use intravascular catheters, Part 1. General requirements.*
- *ISO 10555-1: 1995, Sterile, single-use intravascular catheters, Part 1. General requirements, Amendment 1: 1999*
- *BS/EN/ISO 10555-3: 1997, Sterile, single-use intravascular catheters, Part 3. Central venous catheters*
- *AAMI/ANSI/ISO 11135: 1994, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*
- *AAMI/ANSI/ISO 10993-1: 2003, Biological Evaluation of medical Devices Part 1: Evaluation and Testing, and the FDA Modified ISO 10993 Test Profile*
- *NF S 94-370, French Standard, Surgical Implants, implantable catheter chambers, intravenous, intraarterial, intraperitoneal, intrathecal and epidural use (April 1999)*

Are performance data available to assess effects of new characteristics?

➢ Yes. Verification testing was performed according to protocols based on the above-referenced guidance documents recommendations and additional standards.

Do performance data demonstrate equivalence?

➢ Yes. Performance data gathered in design verification testing demonstrated that the subject PowerPort™ Polymeric Port device is substantially equivalent to the predicate device, the PowerPort™ Titanium Port, K060812, concurrence date July 14, 2006.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

C.R. Bard, Incorporated
Mr. Michaela Rivkowich
Associate Regulatory Affairs Manager
Bard Access Systems, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

JAN 26 2007

Re: K063377
Trade/Device Name: PowerPort™ Implanted Polymeric Port
Regulation Number: 880.5965
Regulation Name: Subcutaneous Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: November 6, 2006
Received: November 8, 2006

Dear Mr. Rivkowich:

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.

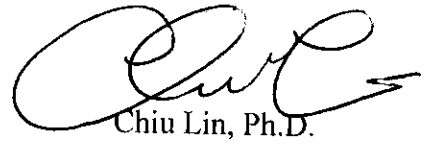
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

Indications for Use

510(k) Number (if known):_____

Device Name: PowerPort™ Implanted Polymeric Port

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.

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.

Prescription Use ___X___ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

K063374