Section 6

510(k) Summary

4 Fr Single Lumen (SL) PowerPICC® Catheter

MAY - 8 2007

Summary of Safety & Effectiveness
Prepared April 23, 2007

General Provisions

Submitter of 510(k) Premarket Notification:	Bard Access Systems, Inc. (BAS) [Subsidiary of C.R. Bard, Inc.] Salt Lake City, Utah 84116 Phone: (801) 595-0700, Ext. 7136 Fax: (801) 595-5425
Contact Person:	Lynn M. Kirchoff Regulatory Affairs Specialist
Device Trade Name:	4 Fr SL **PowerPICC®** Catheter
Device Generic Name:	Peripherally Inserted Central Catheter (PICC)

Predicate Devices

The predicate devices are listed below.

Device Name:	6 Fr TL **PowerPICC®** Catheter
Trade Name:	**PowerPICC®** Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Long Term Intravascular Catheter (80 LJS)
Premarket Notification:	K053501, concurrence date-January 13, 2006

Device Name:	5 Fr SL **PowerPICC®** Catheter
Trade Name:	**PowerPICC®** Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Long Term Intravascular Catheter (80 LJS)
Premarket Notification:	K033389, concurrence date March 14, 2004 K051991, concurrence date October 20, 2005

Classification

21 CFR 880.5970, Class II, 80LJS – Long Term Intravascular Catheter

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Performance Standards

Performance standards have not been established by FDA under section 514 of the Federal Food, Drug and Cosmetic Act.

Intended Use	The **PowerPICC®** Catheters are intended for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling.
Indications for Use	The **PowerPICC®** catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injection of contrast media and allows for central venous pressure monitoring. For blood sampling, infusion or therapy, use a 4 French or larger catheter. The maximum recommended infusion rate is 5ml/sec. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.
Device Description	• The 4 Fr SL PowerPICC® Catheters are open-ended radiopaque polyurethane. • Catheter usable length is 55 cm. • The catheter has a reverse taper design • Catheter shaft tubing is marked with depth indicators, with "0" indicated to serve as a reference for the catheter insertion point. • Catheters are provided sterile in basic and full PICC configurations with legally marketed kit components. • Purple colorants were added to the catheter materials to provide the catheter with an appearance that allows the end user to differentiate Bard's power injectable catheters from other manufacturers' power injectable catheters. • The catheter extension leg, junction and clamp ID tag were printed with markings to identify the catheter as PowerPICC® and to include information to facilitate proper use of the device.
Technological Characteristics	Technological similarities between the subject 4 Fr SL PowerPICC® catheter and the predicate devices remain identical. There are no new questions raised regarding safety or efficacy of the 4 Fr SL PowerPICC®.
Safety and Performance Tests	Biocompatibility requirements of ISO 10993 *Biological Evaluation of Medical Devices Part-1: Evaluation and Testing* and the FDA Modified ISO 10993 Test Profile for externally communicating, blood contacting, long-term devices were met. All materials used in the manufacture of the subject device were previously cleared for similar applications by Bard Access Systems. Performance testing of the 4 Fr SL PowerPICC® catheter was conducted in accordance with the following FDA guidance documents and international standards: • *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, March 16, 1995* • *ISO 10555-1:1997, Sterile, Single-Use Intravascular Catheters, General requirements* • *ISO 10555-1:1997, Sterile, Single-Use Intravascular Catheters, General requirements, Amendment 1* • *ISO 10555-3:1997, Sterile, Single-Use Intravascular Catheters, Central venous catheters* • *AAMI/ANSI/ISO 11135:1994, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*

Safety and Performance Tests Continued

- *AAMI/ANSI/ISO 10993-1:2003, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, and the FDA Modified ISO 10993 Test Profile*
- *IEC 60601-2-34: 2000-10, Medical electrical equipment – Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment*
- *AAMI TIR9: 1992, Evaluation of Clinical Systems for Invasive Blood Pressure Monitoring*
- *ANSI/AAMI BP22: 1994, Blood Pressure Transducers*

Subject product testing has yielded acceptable safety & performance outcomes.

In addition, EO sterilization adoption tests also yielded acceptable results. The results of these tests, in conjunction with the substantial equivalence claims as outlined in the premarket notification, effectively demonstrate the 4 Fr SL PowerPICC® catheters' substantial equivalence to the cited predicate devices.

Summary of Substantial Equivalence

Based on the indications for use, technological characteristics, and safety and performance testing, the subject 4 Fr SL PowerPICC® 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 current commercially available catheters/cited predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2007

Ms. Lynn M. Kirchoff
Regulatory Affairs Specialist
Bard Access Systems, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K070996
Trade/Device Name: 4 Fr Single Lumen (SL) PowerPICC® Catheter
Regulation Number: 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: April 6, 2007
Received: April 9, 2007

Dear Ms. Kirchoff:

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 1.2

Indications for Use Statement

510(k) Number (if known):

Device Name: 4 Fr Single Lumen (SL) **PowerPICC®** Catheter

Indications For Use:

The **PowerPICC®** catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injection of contrast media and allows for central venous pressure monitoring. For blood sampling, infusion or therapy, use a 4 French or larger catheter. The maximum recommended infusion rate is 5ml/sec for power injection of contrast media. For central venous pressure monitoring, it is recommended that catheter lumen of 20 gauge or larger be used.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K070996

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