510(k) Summary
21 CFR 807.92(a)

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OCT 5 2007

PowerPICC SOLO™ Catheter Family
Prepared August 9, 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:	**PowerPICC SOLO™** Catheter
Device Generic Name:	Peripherally Inserted Central Catheter (PICC)

Predicate Devices

Trade Name: **PowerPICC®** Catheter
Common/Usual Name: Peripherally Inserted Central Catheter (PICC)
Classification Name: 80 LJS– Long Term Intravascular Catheter
CFR Reference: 21 CFR §880.5970, Class II
Classification Panel: General Hospital
Premarket Notification: See below

Predicate Device Name	510(k)	Concurrence Date
5 Fr Single Lumen (SL) **PowerPICC®** catheter	K033389	March 14, 2004
6 Fr Dual Lumen (DL) **PowerPICC®** catheter	K050931	June 15, 2005
5 Fr Dual Lumen (DL) **PowerPICC®** catheter	K051672	November 23, 2005
6 Fr Triple Lumen (TL) **PowerPICC®** catheter	K053501	January 13, 2006
4 Fr Single Lumen (SL) **PowerPICC®** catheter	K070996	May 8, 2007
PowerPICC®, Poly Per-Q-Cath, 6 Fr TL Poly Per-Q-Cath, PowerHohn and PowerLines	K051991	October 20, 2005

Trade Name: **PowerGroshong™** PICC Catheter
Common/Usual Name: Peripherally Inserted Central Catheter (PICC)
Classification Name: 80 LJS– Long Term Intravascular Catheter
CFR Reference: 21 CFR §880.5970, Class II
Classification Panel: General Hospital
Premarket Notification: See below

Predicate Device Name	510(k)	Concurrence Date
5 Fr SL **PowerGroshong™** PICC Catheter	K063848	April 4, 2007

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Predicate Devices Continued

Trade Name: **Vaxcel®** PICC with **PASV®** Valve Technology
Common/Usual Name: Peripherally Inserted Central Catheter (PICC)
Classification Name: 80 LJS– Long Term Intravascular Catheter
CFR Reference: 21 CFR §880.5970, Class II
Classification Panel: General Hospital
Premarket Notification: See below

Predicate Device Name	510(k)	Concurrence Date
Vaxcel® PICC with **PASV®** Valve Technology	K021704	June 6, 2002

Classification

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

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 SOLO™** catheters are intended for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling.

The intended use has not changed from the predicate **PowerPICC®** catheters.

Indications for Use

The **PowerPICC SOLO™** 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.

The indications for use have not changed from the predicate **PowerPICC®** catheters.

Device Description

- The **PowerPICC SOLO™** catheter is a clampless proximally valved catheter.
- The **PowerPICC SOLO™** catheters are open-ended radiopaque polyurethane.
- The **PowerPICC SOLO™** catheters are offered in 4 Fr Single Lumen (SL), 5 Fr Single Lumen (SL), 5 Fr Dual Lumen (DL), 6 Fr Dual Lumen (DL), and 6 Fr Triple Lumen (TL) configurations.
- 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

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Device Description Continued	Bard's power injectable catheters from other manufacturers' catheters. • Lower portion of luer hub is blue to identify the catheter as **PowerPICC SOLO™** catheter. • The catheter extension leg, luer hub and junction were printed with markings to identify the catheter as **PowerPICC SOLO™** and to include information to facilitate proper use of the device.
Technological Characteristics	Technological similarities between the subject **PowerPICC SOLO™** catheters and the predicate devices remain identical. There are no new questions raised regarding safety or efficacy of the **PowerPICC SOLO™** catheters.
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 have been met. Performance testing of the **PowerPICC SOLO™** catheters were 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* • *BS/EN/ISO 10555-1: 1997, Sterile, single-use intravascular catheters, Part 1. General requirements* • *ISO 10555-1:2004, Sterile, single-use intravascular catheters, Part 1. General requirements, Amendment 2* • *ASTM F640-79 (reapproved 2000), Standard Test Methods for Radiopacity of Plastics for Medical Use* • *BS/EN/ISO 10555-3:1997, Sterile, single-use intravascular catheters, Part 3. Central venous catheters* • *ISO 594-2: 1998, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings* • *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* • *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. The results of these tests, in conjunction with the substantial equivalence claims as outlined in the premarket notification, effectively demonstrate the **PowerPICC SOLO™** catheters' substantial equivalence to the cited predicate devices.

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Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject **PowerPICC SOLO™** catheters met 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

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lynn M. Kirchoff
Regulatory Affairs Specialist
C.R. Bard, Incorporated
Bard Access Systems
605 North 5600 West
Salt Lake City, Utah 84116

Re: K072230
Trade/Device Name: PowerPICC SOLO™ Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: September 6, 2007
Received: September 7, 2007

Dear Ms. Kirchoff:

This letter corrects our substantially equivalent letter of October 5, 2007.
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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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 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.

In addition, we have determined that your device kit contains chloraprep applicator, alcohol wipes, and lidocaine 1% which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug component[s] of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

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, please contact the Office of Compliance at (240) 276-0141. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (240) 276-3150, 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

510(k) Number (if known): K072230

Device Name: PowerPICC SOLO™ Catheter Family

Indications for Use:

The **PowerPICC SOLO™** 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 ✓ (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)

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

510(k) Number: K072234