BARD
ACCESS SYSTEMS

K102159

NOV 17 2010

510(k) Summary
21 CFR 807.92(a)

PowerPICC® SV Catheter

General Provisions	Submitter Name: Address: Contact Person: Telephone Number: Fax Number: Date of Preparation:	Bard Access Systems, Inc. 605 North 5600 West Salt Lake City, UT 84116 Jessica Agnello Regulatory Affairs Specialist (801) 522-5651 (801) 522-5425 November 4, 2010
Subject Device	Trade Name: Common Name: Classification Name:	**PowerPICC®** SV Catheter Peripherally Inserted Central Catheter (PICC) Percutaneous, implanted, long-term intravascular catheter LJS, 21 CFR § 880.5970 Class II
Predicate Devices	Trade Name: Classification Name: Premarket Notification: Manufacturer:	Poly **Per-Q-Cath®** PICC Catheter Percutaneous, implanted, long-term intravascular catheter, LJS, 21 CFR §880.5970 Class II K034019, K051991 Bard Access Systems, Inc.
	Trade Name: Classification Name: Premarket Notification: Manufacturer:	6F Triple Lumen Poly **Per-Q-Cath®** PICC Catheter Percutaneous, implanted, long-term intravascular catheter, LJS, 21 CFR §880.5970 Class II K043502, K051991 Bard Access Systems, Inc.
	Trade Name: Classification Name: Premarket Notification: Manufacturer:	4F Single Lumen **PowerPICC®** Catheter Percutaneous, implanted, long-term intravascular catheter, LJS, 21 CFR §880.5970 Class II K070996 Bard Access Systems, Inc
	Trade Name: Classification Name: Premarket Notification: Manufacturer:	5F Single Lumen **PowerPICC®** Catheter Percutaneous, implanted, long-term intravascular catheter, LJS, 21 CFR §880.5970 Class II K033389, K051991 Bard Access Systems, Inc

	Trade Name:	6F Triple Lumen **PowerPICC®** Catheter
	Classification Name:	Percutaneous, implanted, long-term intravascular catheter, LJS, 21 CFR §880.5970 Class II
	Premarket Notification:	K053501, K051991
	Manufacturer:	Bard Access Systems, Inc
	Trade Name:	**PowerLine®** Catheters
	Classification Name:	Percutaneous, implanted, long-term intravascular catheter, LJS, 21 CFR §880.5970 Class II
	Premarket Notification:	K093927
	Manufacturer:	Bard Access Systems, Inc
	Trade Name:	**Morpheus®** CT PICC Catheter
	Classification Name:	Percutaneous, implanted, long-term intravascular catheter, LJS, 21 CFR §880.5970 Class II
	Premarket Notification:	K072196
	Manufacturer:	AngioDynamics, Inc

Device Description

The subject **PowerPICC®** SV catheters are members of Bard Access Systems' **PowerPICC®** series of power injectable catheters. The **PowerPICC®** SV catheters are available in 3F single lumen and 4F dual lumen configurations. The catheter extension leg, luer hub and junction are printed with description markings to facilitate proper use of the device. The **PowerPICC®** SV catheters are provided in sterile kit configurations.

Intended Use

The **PowerPICC®** SV 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®** SV catheter is indicated for short or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, power injection of contrast media, and allows for central venous pressure monitoring. For central venous pressure monitoring, it is recommended that a catheter lumen of 20 gauge or larger be used.

Catheter Size	Maximum Flow Rate
3 F Single Lumen	1 mL/sec
4 F Dual Lumen	2.5 mL/sec

Technological Characteristics

Technological characteristics of the subject **PowerPICC®** SV catheters are equivalent with respect to the basic catheter design and function to those of the predicate Poly **Per-Q-Cath®** Catheters. Technical characteristics based on the subject device's power injection capabilities are comparable to the predicate 4F SL **PowerPICC®** catheter and the **Morpheus®** CT PICC catheter. Differences do not raise any new questions regarding safety and effectiveness.

Safety & Performance Tests	Verification and validation activities were designed and performed to demonstrate that the subject **PowerPICC®** SV catheters met predetermined performance specifications. Tests were performed on sterilized, finished devices. 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 Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, March 16, 1995* • *ISO 10555-1:2009, 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 10993-1:2009, 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 of Medical Devices Part 7: Ethylene Oxide Sterilization Results* • *AAMI/ANSI/ISO 11135:2007, Sterilization of Healthcare Products Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* The subject **PowerPICC®** SV catheters met all predetermined acceptance criteria derived from the above mentioned references. Design validation was conducted on the subject **PowerPICC®** SV configuration and yielded acceptable results. Risk management, including a failure modes and effects analysis (FMEA), of the subject device was conducted in accordance with ISO 14971:2007, *Medical Devices – Risk Management for Medical Devices.* No new types of safety or efficacy questions were identified for the subject **PowerPICC®** SV catheters.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject **PowerPICC®** SV catheters met the minimum requirements for its intended use/indications for 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

NOV 17 2010

Re: K102159
Trade/Device Name: PowerPICC® SV Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: November 4, 2010
Received: November 5, 2010

Dear Ms. Agnello:

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.

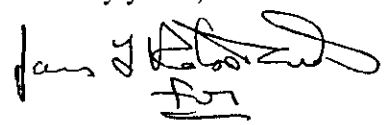
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, general Hospital,
Infection Control and dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

NOV 17 2010

510(k) Number (if known): K102159

Device Name: **PowerPICC®** SV Catheter

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Catheter Size	Maximum Flow Rate
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Prescription Use ✓ 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)

Richard C. Chapman 11/17/10
(Division Sign-Off) Page 1 of 1
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number K102159