Section 5

510(k) Summary
21 CFR 807.92(a)

FEB - 4 2010

PowerLine™ Central Venous Catheters
Prepared February 3, 2010

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) 522-5696 Fax: (801) 522-5425 Contact Person: Sarabjyot Mankoo Regulatory Affairs Specialist Device Trade Name: **5 F DL & 6 F TL PowerLine™** Device Generic Name: Central Venous Catheter (CVC)
Predicate Device	***Primary Predicate:*** Trade Name: **PowerLine™** Common/Usual Name: Central Venous Catheter Classification Name: 80LJS – Long term Intravascular Catheter CFR Reference: 21 CFR §880.5970– Class II Classification Panel: General Hospital Premarket Notification: See table below ***Secondary Predicate:*** Trade Name: **PowerPICC™** Common/Usual Name: Peripherally Inserted Central Catheter (PICC) Classification Name: 80LJS – Long term Intravascular Catheter CFR Reference: 21 CFR §880.5970– Class II Classification Panel: General Hospital Premarket Notification: See table below
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.

Predicate Device Name	510(k)	Concurrence Date
5 F Single Lumen (SL) PowerLine™	K050185	May 26, 2005
6 F Dual Lumen (DL) PowerLine™	K051417	June 30, 2005
CVP Monitoring – PICC & CVC	K051991	October 20, 2005
5F Dual Lumen (DL) PowerPICC™	K051672	November 23, 2005
6F Triple Lumen (TL) PowerPICC™	K053501	January 13, 2006

Intended Use	**PowerLine™** catheters are indicated for short or long term access to the central venous system for intravenous therapy and blood sampling.
Indications for Use	The **PowerLine™** catheter is indicated for short or long term access to the central venous system. PowerLine™ catheters are designed for the administration of I.V. fluids, blood products, drugs, parenteral nutrition solutions, as well as blood withdrawal. In addition, PowerLine™ catheters allow for power injection of contrast media and central venous pressure monitoring. The maximum recommended infusion rate is 5ml/sec. For central venous pressure monitoring, it is recommended that a catheter lumen of 20 gauge or larger be used.
Device Description	The **PowerLine™** catheters are open-ended polyurethane catheters with a reverse taper design. Catheters are available in 5 F Dual-Lumen and the 6 F Triple-Lumen configurations. The usable length of the catheter is 50 cm. Catheter shaft tubing is marked with depth indicators, with "0" indicated to serve as a reference for the catheter insertion point. The catheters have a tissue ingrowth cuff bonded to the catheter shaft. Purple colorants added to the catheter extension legs and shaft aid in distinguishing the catheter as power-injectable. The molded hub is labeled to identify the catheter as **PowerLine™**. The catheter extension leg and clamp are labeled with information to facilitate proper use of the device. The **PowerLine™** catheters are provided in sterile tray configurations.
Technological Characteristics	Technological similarities between the subject **PowerLine™** catheters and the predicate device remain identical. There are no new questions raised regarding safety or efficacy of the subject **PowerLine™** catheters.
Verification & Validation Activities	Verification and validation activities were designed and performed to demonstrate that the subject **PowerLine™** 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 10555-1:1997, Sterile, single-use intravascular catheters, Part 1. General requirements, Amendment 2* • *BS/EN/ISO 10555-3:1997, Sterile, single-use intravascular catheters, Part 3. Central venous catheters* • *AAMI/ANSI/ISO 10993-1:2003, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, and the FDA Modified ISO 10993 Test Profile* • *AAMI/ANSI/ISO 10993-7:1995, Biological Evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Results*

	The subject **PowerLine™** catheters met all predetermined acceptance criteria derived from the above mentioned references. Design validation was conducted on the subject **PowerLine™** 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 **PowerLine™** catheters.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject **PowerLine™** 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

Mr. Sarabjyott Mankoo
Regulatory Affairs Specialist
C. R. Bard, Incorporated
Bard Access Systems
605 North 5600 West
Salt Lake City, Utah 84116

FEB - 4 2010

Re: K093927
Trade/Device Name: PowerLine™ Central Venous Catheters
Regulation Number: 21 CFR 880.5970
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJS
Dated: December 17, 2010
Received: January 5, 2010

Dear Mr. Mankoo:

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,

for

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

510(k) Number (if known):

Device Name: **PowerLine™** Central Venous Catheters

Indications for Use:

The **PowerLine™** catheter is indicated for short or long term access to the central venous system. **PowerLine™** catheters are designed for the administration of I.V. fluids, blood products, drugs, parenteral nutrition solutions, as well as blood withdrawal. In addition, **PowerLine™** catheters allow for power injection of contrast media and central venous pressure monitoring. The maximum recommended infusion rate is 5ml/sec. For central venous pressure monitoring, it is recommended that a 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: K033907