DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 14, 2016

C.R. Bard, Inc.
Mr. Bryan Stone
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, UT 84116

Re: K151985
Trade/Device Name: PowerPICC® EtOH Catheter and PowerPICC SOLO®2 EtOH Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: May 25, 2016
Received: May 26, 2016

Dear Mr. Stone:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control, and
Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151985

Device Name
PowerPICC®EtOH Catheter

Indications for Use *(Describe)*

The PowerPICC®EtOH Catheter is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy including prolonged exposure to intraluminal solutions containing up to 70% ethanol, 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. For central venous pressure monitoring, it is recommended that a catheter lumen of 20 gauge or larger be used.

Catheter Size	Maximum Flow Rate
4F Single Lumen	5 ml/sec
5F Dual Lumen	5 ml/sec
5F Triple Lumen	4 ml/sec

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration

Office of Chief Information Officer Paperwork
Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov*

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151985

Device Name
PowerPICC SOLO®2 EtOH Catheter

Indications for Use *(Describe)*

The PowerPICC SOLO®2 EtOH Catheter is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy including prolonged exposure to intraluminal solutions containing up to 70% ethanol, 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. For central venous pressure monitoring, it is recommended that a catheter lumen of 20 gauge or larger be used.

Catheter Size	Maximum Flow Rate
4F Single Lumen	5 ml/sec
5F Dual Lumen	5 ml/sec
5F Triple Lumen	4 ml/sec

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration

Office of Chief Information Officer Paperwork
Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov*

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

BARD
ACCESS SYSTEMS

510(k) Summary
21 CFR 807.92(a)

General Provisions	Submitter Name: Address:	Bard Access Systems, Inc. 605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Bryan Stone Regulatory Affairs Specialist II
	Telephone Number:	(801) 522-5876
	Fax Number:	(801) 522-5425
	Date of Preparation:	June 30, 2015
Subject Devices	Trade Name:	PowerPICC® EtOH Catheter and PowerPICC SOLO®^{2} EtOH Catheter
	Common Name:	Catheter, Intravascular, Therapeutic, Long-term Greater than 30days
	Classification Name:	Percutaneous, Implanted, Long –term intravascular catheter
	Product Code/ Regulation:	LJS/21 CFR §880.5970
Predicate Devices	Predicate Trade Name: Classification Name: Premarket Notification: Manufacturer:	5F DL PowerPICC® Catheter Percutaneous, Implanted, Long –term intravascular catheter K051672 Bard Access Systems, Inc.
	Predicate Trade Name: Classification Name: Premarket Notification: Manufacturer:	6F TL PowerPICC® Catheter Percutaneous, Implanted, Long –term intravascular catheter K053501 Bard Access Systems, Inc.
	Predicate Trade Name: Classification Name: Premarket Notification: Manufacturer:	4F Single Lumen (SL) PowerPICC® Catheter Percutaneous, Implanted, Long –term intravascular catheter K070996 Bard Access Systems, Inc.

Predicate Trade Name:	PowerPICC SOLO® Catheter Family
Classification Name:	Percutaneous, Implanted, Long –term intravascular catheter
Premarket Notification:	K072230
Manufacturer:	Bard Access Systems, Inc.

Device Description

Bard Access Systems, Inc.'s PowerPICC® EtOH and PowerPICC SOLO®^{2} EtOH Catheters are sterile, single use devices designed to provide access to the patient's vascular system. The devices are intended for short- or long-term use (>30 days) to sample blood and administer fluids intravenously. The catheters are compatible with intraluminal solutions containing up to 70% ethanol, capable of central venous pressure monitoring, and can withstand power injection of contrast media. The catheters are peripherally inserted central catheters (PICC) and utilize the same placement technique as the predicate devices.

The subject devices included in this notification are of varying French size and catheter configuration types, as summarized in the table below.

Summary of Subject Devices	
Catheter Configuration	French size (Number of Lumens)
PowerPICC® EtOH	4F (Single Lumen (SL))
	5F (Dual Lumen (DL)) FT
	5F (Triple Lumen (TL))
PowerPICC SOLO®^{2} EtOH	4F (Single Lumen (SL))
	5F (Dual Lumen (DL)) FT
	5F (Triple Lumen (TL))

The subject catheters will be packaged with legally marketed components used in the placement procedure.

Device Description

The subject devices included in this bundled 510(k) notification are of varying French size and catheter configuration types, and as such, the device descriptions are grouped and organized to capture catheter similarities.

The following device descriptors apply to **all French sizes and configurations** of the subject Bard Access PowerPICC® EtOH and PowerPICC SOLO®2 EtOH Catheters:

- The catheters are open-ended, radiopaque polyurethane;
- The catheters have a reverse taper design;
- Each catheter configuration has one power injectable lumen;
- 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 interventional radiology (IR), and basic, full, and max barrier nursing PICC configurations with legally marketed kit components;
- Purple colorant is included in the catheter material 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;
- Yellow colorant was added to the catheter junction material to provide the catheter with an appearance that allows the end user to differentiate Bard's ethanol compatible catheters from other catheters not compatible with ethanol;
- The catheter extension leg, luer hub, junction, and clamp ID tags are printed with markings to identify the catheter as PowerPICC® EtOH or PowerPICC SOLO®2 EtOH, and include information to facilitate proper use of the device; and
- The PowerPICC® EtOH catheter clamp and PowerPICC SOLO®2 EtOH luer are labeled with EtOH to indicate ethanol compatibility.

The following device descriptors apply to **all French sizes** of the subject Bard Access Systems **PowerPICC® EtOH** Catheters:

- Yellow colorant was added to the catheter extension leg clamp material to provide the catheter with an appearance that allows the end user to differentiate Bard's ethanol compatible catheter from other catheters that are not compatible with ethanol.

Device Description	The following device descriptors apply to **all French sizes** of the subject Bard Access Systems **PowerPICC SOLO®2 EtOH** Catheters: • The PowerPICC SOLO®2 EtOH catheter is a clampless, proximally valved catheter, and • Yellow colorant was added to the lower portion of the luer hub to identify the catheter as a PowerPICC SOLO®2 EtOH catheter that is ethanol compatible. The following device descriptors apply to **specific French sizes** of the subject Bard Access Systems PowerPICC® EtOH and PowerPICC SOLO®2 EtOH Catheters: • The 5F TL catheter product labeling warns against power injection procedures through the two small lumens, • The 5F TL catheter's usable length is 50 cm, • The 5F DL FT and 4F SL catheter's usable length is 55 cm, • The 5 F DL FT catheter has a double taper design, and • The 5 F DL FT catheter product labeling warns against trimming the catheter in the "No Trim Zone" to maintain product functionality.

Intended Use	The PowerPICC® EtOH and PowerPICC SOLO®^{2} EtOH Catheters are intended for short- or long-term peripheral access to the central venous system for intravenous therapy and blood sampling.

Indications For Use

PowerPICC® EtOH Catheter:

The PowerPICC®EtOH Catheter is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy including prolonged exposure to intraluminal solutions containing up to 70% ethanol, 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. For central venous pressure monitoring, it is recommended that a catheter lumen of 20 gauge or larger be used.

Catheter Size	Maximum Flow Rate
4F Single Lumen	5 ml/sec
5F Dual Lumen	5 ml/sec
5F Triple Lumen	4 ml/sec

PowerPICC SOLO®^{2} EtOH Catheter:

The PowerPICC SOLO®^{2} EtOH Catheter is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy including prolonged exposure to intraluminal solutions containing up to 70% ethanol, 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. For central venous pressure monitoring, it is recommended that a catheter lumen of 20 gauge or larger be used.

Catheter Size	Maximum Flow Rate
4F Single Lumen	5 ml/sec
5F Dual Lumen	5 ml/sec
5F Triple Lumen	4 ml/sec

	Technological characteristics of the subject PowerPICC® EtOH and PowerPICC SOLO®[2] EtOH Catheters are substantially equivalent with respect to basic design and function to those of the predicate devices, PowerPICC® (K051672, K053501, and K070996; concurrences November 23, 2005, January 13, 2006, and May 8, 2007, respectively) by Bard Access Systems and PowerPICC SOLO® (K072230, concurrence October 5, 2007) by Bard Access Systems. The subject devices differ in technological characteristics when compared to the predicate devices, and include a change in material formulation, dimensional design, and indications for use.
Technological Characteristics	The indications for use of the subject devices are different compared to the predicate devices in that the subject devices are indicated for prolonged exposure to intraluminal solutions containing up to 70% ethanol. This difference in the indications for use does not alter the intended use of the device (ie., short- or long-term peripheral access to the central venous system for intravenous therapy and blood sampling). The purpose of this information is to clarify to the user the catheter's compatibility with ethanol; it does not prescribe a different general purpose or function of the device, nor does it prescribe a different patient population, therapeutic or diagnostic use of the subject device compared to the predicate device. This technological difference, as well as differences in material formulation and dimensional design, was evaluated using the same test requirements as the predicate devices, as defined in the Risk Assessment. Therefore, these differences in technological characteristics between the subject and predicate devices do not raise different questions of equivalence.

Safety & Performance Tests

Verification and validation tests have been performed in accordance with Design Controls as per 21 CFR §820.30. 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: 2013, Sterile, single-use intravascular catheters, Part 1: General requirements*
- *ISO 10555-3: 2013, Intravascular catheters--Sterile and single-use catheters, Part 3: Central venous catheters*
- *ISO 594-1: 1986, Conical fittings with 6% luer taper for syringes, needles and certain other medical equipment – Part 1: General Requirements*
- *ISO 594-2: 1998, Conical fittings with 6% luer taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings*
- *ISO 10993-1:2009, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, and the FDA Modified ISO 10993 Test Profile*
- *FDA Draft Guidance Use of International Standards ISO 10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (2013)*
- *ISO 10993-7:2008, Biological Evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals*
- *ISO 11135:2014, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*
- *ASTM F640-79 (reapproved 2000): 2012, Standard Test Methods for Radiopacity of Plastics for Medical Use*
- *Design Control Guidance for Medical Device Manufacturers, March 11, 1997*
- *ISO 11607-1: 2006, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
- *ISO 11607-1 AMD 1: 2014, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*

The subject devices met all predetermined acceptance criteria derived from the above listed references and demonstrated substantially equivalent performance as compared to the cited predicate devices.

Risk management, including a failure modes and effects analysis (FMEA), of the subject device was conducted in accordance with ISO 14971:2012, *Medical Devices – Risk Management for Medical Devices.*

Performance Testing- Bench:

- Dimensional Analysis
- Assembly Leak
- Tensile Strength
- Catheter Elongation and Modulus
- Catheter Fatigue
- ISO Luer Compliance
- Visual Inspection
- Gravity Flow
- Priming Volume
- Power Injection
- Burst
- Radiopacity
- Catheter Leak Under Vacuum
- Central Venous Pressure Monitoring
- Stylet Compatibility
- Ink Adherence
- Valve Function

Biocompatibility Testing:

- Cytotoxicity
- Pyrogenicity
- Subacute/Subchronic Toxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity
- Subchronic/Subcutaneous Implant Toxicity
- Genotoxicity Testing
- Implantation studies (2-26 week)
- Hemolysis
- Prothrombin Time Assay
- Unactivated Thromboplastin Time Assay
- Dog Thrombogenicity
- Platelet and Leukocyte Counts

- Compliment Activation
- Chronic Toxicity

Summary of Substantial Equivalence	Based on the intended use, technological characteristics, and safety and performance testing, the subject PowerPICC® EtOH and PowerPICC SOLO®[2] EtOH Catheters met the requirements that are considered sufficient for the intended use and are as safe and as effective as predicate devices cited.