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

April 24, 2017

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

Re: K162441
Trade/Device Name: PowerPICC Provena Catheters with SOLO^2 Valve Technology
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: March 15, 2017
Received: March 17, 2017

Dear Bryan 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,

Tina Kiang
-S

Tina Kiang, Ph.D.
Acting 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)*

K162441

Device Name
PowerPICC Provena Catheters with SOLO^2 Valve Technology

Indications for Use *(Describe)*

The PowerPICC Provena Catheters with SOLO^2 Valve Technology are 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	3 mL/sec
4 F Dual Lumen	5 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.

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ACCESS SYSTEMS

510(k) Summary: K162441

21 CFR 807.92(a)

General Provisions	Submitter Name:	Bard Access Systems, Inc.
	Submitter Address:	605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Bryan Stone Associate Manager, Regulatory Affairs
	Telephone Number:	(801) 522-5876
	Fax Number:	(801) 522-5425
	Date of Preparation:	April 17, 2017
Subject Device	Trade Name(s):	PowerPICC Provena Catheters with SOLO^2 Valve Technology
	Common Name:	Peripherally Inserted Central Catheter (PICC)
	Classification Name:	percutaneous, implanted, long–term intravascular catheter
	Product Code/Regulation/Class:	LJS/21 CFR §880.5970/Class II
Predicate Device	Predicate Trade Name:	PowerPICC Provena Catheter
	Classification Name:	percutaneous, implanted, long–term intravascular catheter
	Product Code/Regulation/Class:	LJS/21 CFR §880.5970/Class II
	Premarket Notification:	K162443
	Manufacturer:	Bard Access Systems, Inc.
Reference Device	Reference Trade Name:	PowerPICC SOLO Catheter
	Classification Name:	percutaneous, implanted, long–term intravascular catheter
	Product Code/Regulation/Class:	LJS/21 CFR §880.5970/Class II
	Premarket Notification:	K072230
	Manufacturer:	Bard Access Systems, Inc.

<table>
<tr><td>Device Description</td><td>
Bard Access Systems, Inc.'s PowerPICC Provena Catheters with SOLO^2 Valve Technology are sterile, single use devices designed to provide access to the patient's vascular system. The devices are intended for long or short-term use, as clinically indicated, to sample blood and administer fluids intravenously. The catheters are 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 device. The subject devices include a silicone valve on the proximal end.

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

<table>
<tr><th colspan="2">Summary of Subject Devices</th></tr>
<tr><th>Catheter Configuration</th><th>French size (Number of Lumens)</th></tr>
<tr><td rowspan="2">PowerPICC Provena Catheters with SOLO^2 Valve Technology</td><td>3 French Single Lumen (SL)</td></tr>
<tr><td>4 French Dual Lumen (DL)</td></tr>
</table>
The following device descriptors apply to all French sizes and configurations of the subject catheters:
• Catheters are open-ended, radiopaque polyurethane;
• Catheters incorporate a silicone valve on the proximal end;
• Catheters have 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;
• 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;
• Catheter extension legs, luer hubs, and junction are printed with markings to identify the catheter as PowerPICC Provena Catheters with SOLO^2 Valve Technology, and include information to facilitate proper use of the device.

The subject devices are provided sterile in basic interventional radiology (IR) kits, as well as basic, full, and max barrier nursing PICC kits with legally marketed components to assist in the placement procedure. These kits are available in both standard and small patient versions.
</td></tr>
<tr><td>Intended Use</td><td>The PowerPICC Provena Catheters with SOLO^2 Valve Technology are intended for short- or long-term peripheral access to the central venous system for intravenous therapy and blood sampling.</td></tr>
</table>

<table>
<tr>
<td>Indications For Use</td>
<td>The PowerPICC Provena Catheters with SOLO^2 Valve Technology are indicated for short or long-term use when clinically indicated and for 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.
<table>
<tr><th>Catheter Size</th><th>Maximum Flow Rate</th></tr>
<tr><td>3F Single Lumen</td><td>3 mL/sec</td></tr>
<tr><td>4F Dual Lumen</td><td>5 mL/sec</td></tr>
</table>
</td>
</tr>
</table>

Technological Characteristics

Technological characteristics of the subject PowerPICC Provena Catheters with SOLO^2 Valve Technology are substantially equivalent with respect to basic design and function to those of the cited primary predicate device.

Key modifications made to the subject device when compared to the predicate device are as follows:

- The luer hub of the subject catheters has been modified by adding a proximal valve. This luer and valve is identical to the valve used in the reference device – the PowerPICC SOLO Catheter, K072230.
- Labeling and packaging modifications due to the commercial name change have been made.

The following table provides a comparison between the subject and predicate device.

Subject and Predicate Device Comparison Table			
Attribute	**Subject Device – PowerPICC Provena Catheter With SOLO^2 Valve Technology**	**Predicate Device – PowerPICC Provena Catheters (K162443)**	**Reference Device – PowerPICC SOLO Catheters (K072230)**
Owner	Same	Bard Access Systems, Inc.	Bard Access Systems, Inc.
Classification	Same	LJS - 21 CFR 880.5970 – Long-Term - Intravascular Catheter	LJS - 21 CFR 880.5970 – Long-Term - Intravascular Catheter
510(k) Status	Subject of this Premarket Notification	K162443 – Concurrence date October 25, 2016	K072230 - Concurrence date October 05, 2007

Subject and Predicate Device Comparison Table

Attribute	Subject Device – PowerPICC Provena Catheter With SOLO² Valve Technology	Predicate Device – PowerPICC Provena Catheters (K162443)	Reference Device – PowerPICC SOLO Catheters (K072230)
Indications for Use	The PowerPICC Provena Catheters with SOLO² Valve Technology are indicated for short or long-term use when clinically indicated and for 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: 3F Single Lumen — Maximum Flow Rate: 3 mL/sec Catheter Size: 4F Dual Lumen — Maximum Flow Rate: 5 mL/sec	The PowerPICC Provena Catheters are 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: 3F Single Lumen — Maximum Flow Rate: 3 mL/sec Catheter Size: 4F Dual Lumen — Maximum Flow Rate: 5 mL/sec	The PowerPICC SOLO catheters are 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 4F 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 a catheter lumen of 20 gauge or larger be used.
Commercial Name	PowerPICC Provena Catheters with SOLO² Valve Technology	PowerPICC Provena Catheters	PowerPICC SOLO Catheter
Catheter Dimensions	Same as Predicate	3F Single Lumen x 55 cm 4F Dual Lumen x 55 cm	4F Single Lumen x 55 cm 5F Dual Lumen x 55 cm
Duration of Use	Same	Short (<30 days) or long-term (>30 days)	Short (<30 days) or long-term (>30 days)

Subject and Predicate Device Comparison Table			
Attribute	**Subject Device – PowerPICC Provena Catheter With SOLO² Valve Technology**	**Predicate Device – PowerPICC Provena Catheters (K162443)**	**Reference Device – PowerPICC SOLO Catheters (K072230)**
Means of Insertion	Same	Percutaneous using a peel-away sheath Introducer	Percutaneous using a peel-away sheath Introducer
Insertion Site	Same	Peripheral	Peripheral
Primary Device Materials	*Catheter Base Materials* Shaft Tubing: Same as Predicate Luer Connector: Same as Reference Extension Legs: Same as Predicate Junction Same as Predicate	*Catheter Base Materials* Shaft Tubing: Polycarbonate Polyurethane Luer Connector: Polyurethane Extension Legs: Polycarbonate Polyurethane Junction: Polycarbonate Polyurethane	Catheter Base Materials Shaft Tubing: Polyether Polyurethane Luer Connector: Polyurethane with Silicone Valve Extension Legs: Polyether Polyurethane Junction: Polyether Polyurethane
Catheter Proximal Configuration	Luer Connection with Valve The subject device differs from its primary predicate in terms of the luer hub with valve configuration on the subject device. This difference in the luer does not alter the intended use of the subject device, nor does it raise different questions of equivalence. The luer hub on the subject device is identical to that of the reference device.	Luer Connection	Luer Connection with Valve

<table>
<tr><th colspan="4">Subject and Predicate Device Comparison Table</th></tr>
<tr><th>Attribute</th><th>Subject Device – PowerPICC Provena Catheter With SOLO² Valve Technology</th><th>Predicate Device – PowerPICC Provena Catheters (K162443)</th><th>Reference Device – PowerPICC SOLO Catheters (K072230)</th></tr>
<tr><td>Catheter Distal Configuration</td><td>Same</td><td>Open Ended</td><td>Open Ended</td></tr>
<tr><td>Number of Lumens</td><td>Same</td><td>Single Lumen
Dual Lumen</td><td>Single Lumen
Dual Lumen</td></tr>
<tr><td>Power Injection Maximum Flow Rate</td><td>Same as Predicate</td><td><table><tr><th>Catheter Size</th><th>Maximum Flow Rate</th></tr><tr><td>3F Single Lumen</td><td>3 mL/sec</td></tr><tr><td>4F Dual Lumen</td><td>5 mL/sec</td></tr></table></td><td><table><tr><th>Catheter Size</th><th>Maximum Flow Rate</th></tr><tr><td>4F Single Lumen</td><td>5 mL/sec</td></tr><tr><td>5F Dual Lumen</td><td>5 mL/sec</td></tr></table></td></tr>
<tr><td>Sterility</td><td>Same</td><td>Provided Sterile</td><td>Provided Sterile</td></tr>
<tr><td>Packaging Configurations</td><td>Same as Predicate</td><td>Both Standard and Small Patient versions of the following configurations:
Basic Configuration
Full Configuration
Max Barrier Configuration
IR Configuration</td><td>Standard Kits:
Basic Configuration
Full Configuration
Max Barrier Configuration
IR Configuration</td></tr>
</table>

The technological differences listed above were evaluated using the same test requirements as the predicate device, 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.

Performance Tests

Verification and validation tests were designed and performed in accordance with Design Controls per 21 CFR §820.30. The following tests were conducted per guidance documents and standards in conjunction with in-house protocols to establish the performance of the device.

Verification / Validation Method	Risk Acceptability Criteria (Acceptance Criteria of Test)
Mechanical Hemolysis Test	Testing to determine the hemolytic properties when blood is aspirated through the catheter assembly. • Bard internal standards and procedures
Dimensional Test	Test to measure OD and ID for single lumen catheters and OD and lumen area for dual lumen catheters to ensure compliance with dimensional specification. • Bard internal standards and procedures and *ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements*
Catheter Collapse Test	Test to measure the flow rate of aspiration and demonstrate that the catheter will not collapse under a vacuum. • Bard internal standards and procedures and FDA guidance, *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters (March 16, 1995)*
Luer to Extension Leg Tensile Test	Test to demonstrate the peak tensile force of each test piece exceeds the minimum peak tensile force. • *ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements*
Priming Volume	Test to measure the volume required to prime a full length catheter. • FDA guidance, *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters (March 16, 1995)*
Pump Flow	Test to determine the maximum pressure generated by the catheter when infusing water through it at a maximum pump flow rate. • Bard internal standards and procedures
Gravity Flow	Test to measure the gravity flow rate. • Bard internal standards and procedures and FDA guidance, *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*

The subject devices met all predetermined acceptance criteria derived from the above listed references and demonstrated substantial equivalence as compared to the cited predicate device.

Risk management, including a failure modes and effects analysis (FMEA), of the subject devices was conducted in accordance with BS EN ISO 14971:2012, Medical Devices – Application of Risk Management to Medical Devices.

Summary of Substantial Equivalence

Based on the indications for use, technological characteristics, and results of performance testing, the subject PowerPICC Provena Catheters with SOLO^2 Valve Technology meet the requirements that are considered sufficient for its intended use and demonstrate substantial equivalence to the cited predicate device.