April 26, 2018

C.R. Bard, Inc (Bard has joined BD)
Bryan Stone
Associate Manager, Regulatory Affairs
605 North 5600 West
Salt Lake City, Utah 84116

Re: K180548
Trade/Device Name: PowerPICC Provena Catheters
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: February 27, 2018
Received: March 1, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180548

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.

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."

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510(k) Summary K180548

21 CFR 807.92(a)

General Provisions	Submitter Name:	Bard Access Systems, Inc. (Bard has joined BD)
	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 19, 2018
Subject Devices	Trade Name(s):	PowerPICC Provena Catheters PowerPICC Provena Catheters with SOLO^2 Valve Technology
	Common Name:	Catheter, Intravascular, Therapeutic, Long-term Greater than 30 days
	Classification Name:	Percutaneous, Implanted, Long–term intravascular catheter
	Product Code/Regulation:	LJS/21 CFR §880.5970
	Class	2
	Classification Panel	General Hospital
Predicate Devices	Predicate Trade Name:	PowerPICC Provena Catheters PowerPICC Provena Catheters with SOLO^2 Valve Technology
	Classification Name:	Percutaneous, Implanted, Long–term intravascular catheter
	Product Code/Regulation:	LJS/21 CFR §880.5970
	Premarket Notification #:	K162443 (PowerPICC Provena) K162441 (PowerPICC Provena Catheters with SOLO^2 Valve Technology)
	Manufacturer:	Bard Access Systems, Inc.
Reference Device	Reference Trade Name:	PowerPICC SOLO Catheter
	Classification Name:	Percutaneous, Implanted, Long–term intravascular catheter
	Product Code/Regulation:	LJS/21 CFR §880.5970
	Premarket Notification:	K072230
	Manufacturer:	Bard Access Systems, Inc.

<table>
<tr><td>Device Description</td><td>The PowerPICC Provena Catheters and 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 short- or long-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 SOLO^2 versions of the subject devices include a silicone valve on the proximal end.

The subject devices are provided sterile in basic interventional radiology (IR) 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 and 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>
<tr><td>Indications For Use</td><td>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.
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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.
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</table>

Technological Characteristics

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

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

- The material formulation of the extension leg has been changed from Polycarbonate Polyurethane to Polyether Polyurethane.

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

Attribute	Subject Devices – PowerPICC Provena Catheters and PowerPICC Provena Catheters With SOLO^2 Valve Technology	Predicate Devices – PowerPICC Provena Catheters (K162443); PowerPICC Provena Catheters with SOLO^2 Valve Technology (K162441)
Owner	Same	Bard Access Systems, Inc. (Bard has joined BD)
Classification	Same	LJS - 21 CFR 880.5970 – Long-Term - Intravascular Catheter
510(k) Status	Subjects of this Premarket Notification	K162443 – Concurrence date October 25, 2016 K162441 – Concurrence date April 24, 2017

<table>
<tr><td></td><td>
<table>
<tr><td>Indications for Use</td><td>Same</td><td>
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.
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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.
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<tr><td>4F Dual Lumen</td><td>5 mL/sec</td></tr>
</table>
</td></tr>
<tr><td>Commercial Name</td><td>Same</td><td>PowerPICC Provena Catheters
PowerPICC Provena Catheters with SOLO^2 Valve Technology</td></tr>
<tr><td>Catheter Dimensions</td><td>Same</td><td>3F Single Lumen x 55 cm
4F Dual Lumen x 55 cm</td></tr>
</table>
</td></tr>
</table>

Duration of Use	Same	Short (<30 days) or long-term (>30 days)
Means of Insertion	Same	Percutaneous using a peel-away sheath Introducer
Insertion Site	Same	Peripheral
Primary Device Materials	*Catheter Base Materials* Shaft Tubing: Same Luer Connector: Same Extension Legs: Polyether Polyurethane Junction: Same Valve (SOLO^2 Only): Same	*Catheter Base Materials* Shaft Tubing: Polycarbonate Polyurethane Luer Connector: Polyurethane Extension Legs: Polycarbonate Polyurethane Junction: Polycarbonate Polyurethane (inner) Polyether Polyurethane (outer) Valve (SOLO^2 Only): Silicone
Catheter Proximal Configuration	Same	Luer Connection Luer Connection with Valve (SOLO^2)
Catheter Distal Configuration	Same	Open Ended
Number of Lumens	Same	Single Lumen Dual Lumen

<table>
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<tr><td>Power Injection Maximum Flow Rate</td><td>Same</td><td>
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<tr><th>Catheter Size</th><th>Maximum Flow Rate</th></tr>
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<tr><td>4F Dual Lumen</td><td>5 mL/sec</td></tr>
</table>
</td></tr>
<tr><td>Sterility</td><td>Same</td><td>Provided Sterile</td></tr>
<tr><td>Packaging Configurations</td><td>Same</td><td>Both Standard and Small Patient versions of the following configurations:
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 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 safety or effectiveness.
</td></tr>
<tr><td>Performance Tests</td><td>
Based on a risk analysis, the performance tests completed on the subject device were limited to those tests required to support a determination of substantial equivalence to the predicate device. In addition, when technological characteristics between the subject and predicate device were found to be identical, results of the performance testing conducted on the predicate device were applied to the subject device. The following table identifies the performance tests completed on the subject device based upon the specific modification to the extension leg material, including a test description and applicable standard associated with each test.
<table>
<tr><th>Verification / Validation Method</th><th>Risk Acceptability Criteria (Acceptance Criteria of Test)</th></tr>
<tr><td>Assembly Tensile Testing</td><td>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</td></tr>
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<tr><td></td><td>
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<tr><td>Dimensional Characterization</td><td>Test to demonstrate that the new material formulation conforms correctly to design tolerances of the extension legs.
BAS internal standards and procedures</td></tr>
<tr><td>Leak Decay Testing</td><td>Testing performed to evaluate that the catheter assembly will not leak when the distal end of the catheter is occluded.
BAS internal standards and procedures and ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements</td></tr>
<tr><td>Hydraulic Burst Testing</td><td>Testing performed to evaluate that the catheter burst pressure exceeds the peak use pressure at maximum flow conditions.
BAS internal standards and procedures and ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements</td></tr>
</table>
A biocompatibility evaluation was also conducted based upon the specific modification to the subject device per ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process. According to this evaluation, and the tests and references mentioned above, the subject devices met design requirements and demonstrated substantial equivalence as compared to the cited predicate devices. This biocompatibility evaluation also utilized the information from the reference device PowerPICC SOLO (K072230), which uses the same material for the extension legs as the subject devices.

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.
</td></tr>
<tr><td>Summary of Substantial Equivalence</td><td>Based on the risk management activities, the subject PowerPICC Provena Catheters and PowerPICC Provena Catheters with SOLO^2 Valve Technology have been demonstrated to be substantially equivalent to the cited predicate devices.</td></tr>
</table>