



Food and Drug Administration
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October 25, 2016

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

Re: K162443
Trade/Device Name: PowerPICC Provena Catheters
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: September 28, 2016
Received: September 30, 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,

 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

Indications for Use

510(k) Number (if known)

K162443

Device Name

PowerPICC Provena Catheters

Indications for Use (Describe)

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	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**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 Regulatory Affairs Specialist, II
	Telephone Number:	(801) 522-5876
	Fax Number:	(801) 522-5425
	Date of Preparation:	September 29, 2016
Subject Device	Trade Name(s):	PowerPICC Provena Catheters
	Common Name:	Peripherally Inserted Central Catheter (PICC)
	Classification Name:	Percutaneous, Implanted, Long-term Intravascular Catheter
	Product Code/Regulation:	LJS/21 CFR §880.5970
Predicate Devices	Predicate Trade Name:	PowerPICC SV Catheter
	Classification Name:	Percutaneous, Implanted, Long-term Intravascular Catheter
	Premarket Notification:	K102159
	Manufacturer:	Bard Access Systems, Inc.
References Devices	Reference Trade Name:	PowerPICC EtOH Catheter
	Classification Name:	Percutaneous, Implanted, Long-term Intravascular Catheter
	Premarket Notification:	K151985
	Manufacturer:	Bard Access Systems, Inc.
	Reference Trade Name:	PowerPICC Catheter
	Classification Name:	Percutaneous, Implanted, Long-term Intravascular Catheter
	Premarket Notification:	K053501
	Manufacturer:	Bard Access Systems, Inc.
Device Description	Bard Access Systems, Inc.'s PowerPICC Provena Catheters are sterile, single use devices designed to provide access to the patient's vascular system. The devices are	

	<p>intended for short- or long-term use (>30 days) 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 devices.</p> <p>The subject devices included in this notification are of varying French size and catheter configuration types, as summarized in the table below.</p> <table border="1" data-bbox="513 464 1427 619"> <thead> <tr> <th colspan="2">Summary of Subject Devices</th> </tr> <tr> <th>Catheter Configuration</th> <th>French size (Number of Lumens)</th> </tr> </thead> <tbody> <tr> <td rowspan="2">PowerPICC Provena Catheters</td> <td>3 French Single Lumen (SL)</td> </tr> <tr> <td>4 French Dual Lumen (DL)</td> </tr> </tbody> </table> <p>The following device descriptors apply to all French sizes and configurations of the subject catheters:</p> <ul style="list-style-type: none"> • Catheters are open-ended, radiopaque polyurethane; • 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; and • Catheter extension leg, luer hub, junction, and clamp ID tags are printed with markings to identify the catheter as PowerPICC Provena Catheters, and include information to facilitate proper use of the device. <p>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.</p>	Summary of Subject Devices		Catheter Configuration	French size (Number of Lumens)	PowerPICC Provena Catheters	3 French Single Lumen (SL)	4 French Dual Lumen (DL)
Summary of Subject Devices								
Catheter Configuration	French size (Number of Lumens)							
PowerPICC Provena Catheters	3 French Single Lumen (SL)							
	4 French Dual Lumen (DL)							
<p>Intended Use</p>	<p>The PowerPICC Provena Catheters are intended for short- or long-term peripheral access to the central venous system for intravenous therapy and blood sampling.</p>							
<p>Indications For Use</p>	<p>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.</p> <table border="1" data-bbox="748 1587 1284 1755"> <thead> <tr> <th>Catheter Size</th> <th>Maximum Flow Rate</th> </tr> </thead> <tbody> <tr> <td>3F Single Lumen</td> <td>3 mL/sec</td> </tr> <tr> <td>4F Dual Lumen</td> <td>5 mL/sec</td> </tr> </tbody> </table>	Catheter Size	Maximum Flow Rate	3F Single Lumen	3 mL/sec	4F Dual Lumen	5 mL/sec	
Catheter Size	Maximum Flow Rate							
3F Single Lumen	3 mL/sec							
4F Dual Lumen	5 mL/sec							
<p>Technological Characteristics</p>	<p>Technological characteristics of the subject PowerPICC Provena Catheters are substantially equivalent with respect to basic design and function to those of the cited predicate device.</p>							

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

- Dimensional modifications to the catheter shaft including the reverse taper length and wall thickness of the catheter lumens;
- Material formulation changes have been made to the subject devices compared to the predicate devices (refer to Comparison Table below);
- Labeling and packaging modifications due to changes to the commercial name, maximum flow rate, and the addition of small patient packaging kit configurations.

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

Subject and Predicate Device Comparison Table			
Attribute	Subject Device – PowerPICC Provena Catheters		Predicate Device – PowerPICC SV Catheters (K102159)
Owner	Same		Bard Access Systems, Inc.
Classification	Same		LJS - 21 CFR 880.5970 – Long-Term - Intravascular Catheter
510(k) Status	Subject of this Premarket Notification		K102159 - Concurrence date November 17, 2010
Indications for Use	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.		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
		3F Single Lumen	3 mL/sec
		4F Dual Lumen	5 mL/sec
Commercial Name	PowerPICC Provena Catheters		PowerPICC SV Catheters
Catheter Dimensions	3F Single Lumen x 55 cm 4F Dual Lumen x 55 cm		3F Single Lumen x 45 cm 4F Dual Lumen x 55 cm
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	<i>Catheter Base Materials</i> <u>Shaft Tubing:</u> Polycarbonate Polyurethane <u>Luer Connector:</u> Same <u>Extension Legs:</u> Polycarbonate Polyurethane <u>Junction</u> Same		<i>Catheter Base Materials</i> <u>Shaft Tubing:</u> Polyether Polyurethane <u>Luer Connector:</u> Polyurethane <u>Extension Legs:</u> Polyether Polyurethane <u>Junction</u> Polyether Polyurethane	
	Catheter Proximal Configuration	Same		Luer Connection	
	Catheter Distal Configuration	Same		Open Ended	
	Number of Lumens	Same		Single Lumen Dual Lumen	
	Power Injection Maximum Flow Rate	Catheter Size	Maximum Flow Rate	Catheter Size	Maximum Flow Rate
		3F Single Lumen	3 mL/sec	3F Single Lumen	1 mL/sec
		4F Dual Lumen	5 mL/sec	4F Dual Lumen	2.5 mL/sec
	Sterility	Same		Provided Sterile	
Packaging Configurations	Both Standard and Small Patient versions in: <ul style="list-style-type: none"> • Basic Configuration • Full Configuration • Max Barrier Configuration • IR Configuration 		Standard Kits: <ul style="list-style-type: none"> • Basic Configuration • Full Configuration • Max Barrier Configuration • IR Configuration 		
The technological differences listed above, including differences in material formulation and dimensional design, 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 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)
Biocompatibility Testing	<p>Tests to confirm that the catheter is free from biological hazard.</p> <ul style="list-style-type: none"> Bard internal standards and procedures and <i>ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements</i> <p>Testing Performed includes:</p> <ul style="list-style-type: none"> Sensitization Cytotoxicity Irritation/Intracutaneous Reactivity Acute Systemic Injection Material-mediated Pyrogenicity Subacute 14 day IV toxicity (Saline) Subacute 14 day IP toxicity (Cottonseed oil) Ames Genotoxicity Mouse Lymphoma Rodent Blood Micronucleus 2 week and 6 week implantation Hemolysis Complement Activation
Cantilever Stiffness Test	<p>Test to characterize the catheter shaft stiffness at the distal section using a cantilever bend technique.</p> <ul style="list-style-type: none"> Bard internal standards and procedures
Clamp Engagement	<p>Test to confirm that the catheter assembly will not leak when the clamp is engaged.</p> <ul style="list-style-type: none"> Bard internal standards and procedures and <i>ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements</i>
Mechanical Hemolysis Test	<p>Testing to determine the hemolytic properties when blood is aspirated through the catheter assembly.</p> <ul style="list-style-type: none"> Bard internal standards and procedures
Leak Test	<p>Test to confirm that the catheter assembly will not leak when the distal end of the catheter is occluded.</p> <ul style="list-style-type: none"> Bard internal standards and procedures and <i>ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements</i>
Dimensional Test	<p>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.</p> <ul style="list-style-type: none"> Bard internal standards and procedures and <i>ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements</i>
Implantable Length	<p>Test to measure useful length for catheters to ensure compliance with dimensional specification.</p> <ul style="list-style-type: none"> Bard internal standards and procedures and <i>ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements</i>
Extension Leg Length	<p>Test to measure and confirm extension leg length compliance with dimensional specification.</p> <ul style="list-style-type: none"> Bard internal standards and procedures
Catheter Collapse Test	<p>Test to measure the flow rate of aspiration and demonstrate that the catheter will not collapse under a vacuum.</p> <ul style="list-style-type: none"> Bard internal standards and procedures and <i>ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements</i>

Burst Test	Burst pressure test to confirm the catheter burst pressure exceeds the peak pressure present in the catheter at maximum flow conditions when the distal end is occluded. <ul style="list-style-type: none"> Bard internal standards and procedures and <i>ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements</i>
OD Swell	Test to confirm that the catheter does not swell beyond twice the size of the labeled OD during power injection. <ul style="list-style-type: none"> Bard internal standards and procedures
Hydraulic Catheter Burst Test	Burst pressure test to confirm the catheter burst pressure exceeds the peak pressure present in the catheter at maximum flow conditions when the distal end is occluded. <ul style="list-style-type: none"> Bard internal standards and procedures and <i>ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements</i>
Extension Leg Burst Test	Burst pressure test to confirm the extension leg burst pressure exceeds the peak pressure present in the catheter at maximum flow conditions when the extension leg is occluded. <ul style="list-style-type: none"> Bard internal standards and procedures and <i>ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements</i>
Power Injection Conditioning	Test to confirm the catheter does not leak or burst as a result of power injections at maximum indicated flow rate. <ul style="list-style-type: none"> Bard internal standards and procedures and <i>ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements</i>
Tip Stability Test	Test to confirm that the catheter tip remains in the same orientation during power injection (tip pointing in direction of venous flow) at the maximum indicated flow rate. <ul style="list-style-type: none"> Bard internal standards and procedures
Assembly Tensile Test	Test to demonstrate the peak tensile force of each test piece exceeds the minimum peak tensile force. <ul style="list-style-type: none"> <i>ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements</i>
Shaft Tensile Test	
Luer to Extension Leg Tensile Test	
Shaft Tensile Test	Test to evaluate the maximum catheter strain and modulus at break. <ul style="list-style-type: none"> Bard internal standards and procedures and FDA guidance, <i>Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters (March 16, 1995)</i>
Radiopacity	Test to demonstrate catheter radio-detectability. <ul style="list-style-type: none"> Bard internal standards and procedures and <i>ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements</i>
Suture Wing Integrity Test	Test to measure the maximum force a catheter junction suture wing can withstand prior to break. <ul style="list-style-type: none"> Bard internal standards and procedures and FDA guidance, <i>Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters (March 16, 1995)</i>
Priming Volume	Test to measure the volume required to prime a full length catheter. <ul style="list-style-type: none"> FDA guidance, <i>Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters (March 16, 1995)</i>
Gravity Flow	Test to measure the gravity flow performance of a full length catheter. <ul style="list-style-type: none"> Bard internal standards and procedures and <i>ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements</i>

	Pump Flow	Test to determine the maximum pressure generated by the catheter when infusing water through it at a maximum pump flow rate. <ul style="list-style-type: none"> • Bard internal standards and procedures
	Kink Diameter Test	Test to quantitatively evaluate kink characteristics associated with the catheter shafts. <ul style="list-style-type: none"> • Bard internal standards and procedures
	Stylet Drag Test	Test to ensure that the stylets used to place the catheter can be removed without difficulty. <ul style="list-style-type: none"> • Bard internal standards and procedures
	StatLock Compatibility	Test to ensure the catheter is compatible with StatLock for catheter securement. <ul style="list-style-type: none"> • Bard internal standards and procedures
	Taper Length	Test to measure and confirm taper length compliance with dimensional specification. <ul style="list-style-type: none"> • Bard internal standards and procedures
	Catheter Printing	Test is to confirm ink on the catheter exhibits proper adherence. <ul style="list-style-type: none"> • Bard internal standards and procedures
	<p>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.</p> <p>Risk management, including a failure modes and effects analysis (FMEA), of the subject device was conducted in accordance with BS EN ISO 14971:2012, Medical Devices – Application of Risk Management to Medical Devices.</p>	
Summary of Substantial Equivalence	<p>Based on the indications for use, technological characteristics, and results of performance testing, the subject PowerPICC Provena Catheters meet the requirements that are considered sufficient for its intended use and demonstrate substantial equivalence to the cited predicate device.</p>	