July 30, 2021

Bard Access Systems, Inc.
Mary Strickland
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, Utah 84116

Re: K210264
Trade/Device Name: PowerPICC Catheter
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: June 28, 2021
Received: June 30, 2021

Dear Mary Strickland:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CAPT Alan M. Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210264

Device Name

PowerPICC Catheter

Indications for Use *(Describe)*
The PowerPICC 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. The maximum infusion flow rate is 5mL/second for power injection of contrast media. For central venous pressure monitoring, it is recommended that a catheter lumen of 20gauge or larger be used.

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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K210381 510(k) Summary for PowerPICC Catheters

21 CFR §807.92(a)

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part(I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based on is presented in the following table:

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:	Mary Strickland Regulatory Affairs Specialist
	Telephone Number:	801.522.5031
	Fax Number:	801.522.5425
	Date of Preparation:	7/30/2021
Subject Device	Trade Name(s):	PowerPICC Catheter
	Common Name:	Catheter, Intravascular, Therapeutic, Long-term Greater than 30 days
	Classification Name:	Percutaneous, Implanted, Long-term Intravascular Catheter
	Class:	Class 2
	Regulation Number:	21 CFR §880.5970
	Product Code:	LJS
	Classification Panel	General Hospital
Predicate Device	Trade Name(s):	PowerPICC SOLO Catheter
	Common Name:	Catheter, Intravascular, Therapeutic, Long-term Greater than 30 days
	Classification Name:	Percutaneous, Implanted, Long-term Intravascular Catheter
	Premarket Notification #	K072230
	Class:	Class 2
	Regulation Number:	21 CFR §880.5970

<table>
<tr><td></td><td>Product Code:
Classification Panel
Concurrence Date:</td><td>LJS
General Hospital
November 18, 2008</td></tr>
<tr><td>Device Description</td><td colspan="2">A family of peripherally inserted central catheters made from specially formulated and processed medical grade materials. Each PowerPICC® catheter has a kink resistant, reverse tapered design. Catheters are packaged in a tray with accessories for reliable long (greater than 30 days) or short (less than 30 days) term vascular access.</td></tr>
<tr><td>Intended Use</td><td colspan="2"><u>PowerPICC Family Catheters:</u>
The PowerPICC catheter is intended to provide short-term access (< 30 days) and long-term access (> 30 days) to the central venous system. They are designed for administering I.V. fluids, blood products, drugs, and parenteral nutrition solutions, as well as blood withdrawal, central venous pressure monitoring, and power injection of contrast media</td></tr>
<tr><td>Indications for Use</td><td colspan="2"><u>PowerPICC Family Catheters</u>
The PowerPICC 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. The maximum infusion flow rate is 5 mL/second 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.</td></tr>
<tr><td>Technological Characteristics</td><td colspan="2">Technological characteristics of the subject PowerPICC Family Catheters are substantially equivalent with respect to basic design, function, and fundamental scientific technology to those of the cited predicate device. Changes compared to the predicate device include a clarification to the indications for use statement, the addition of 5F Triple Lumen and 5Fr Dual Lumen FT catheter configurations, and other minor changes to product instructions for use.
The following table provides a summary comparison between the subject and predicate device:
<table>
<tr><th>Attribute</th><th>Subject Device</th><th>Predicate device</th></tr>
<tr><td>Owner</td><td>Bard Access Systems, Inc.</td><td>Same</td></tr>
<tr><td>510(k) status</td><td>Subject of this 510(k)</td><td>K072230</td></tr>
<tr><td>Device Configuration</td><td><u>PowerPICC SOLO Catheters:</u>
4F Single Lumen (SL), 55 cm Length
5F Dual Lumen (DL), 55 cm Length
5F Dual Lumen (DL) FT, 55 cm Length, (4F between 5 and 30cm mark)</td><td><u>PowerPICC SOLO Catheters:</u>
4F Single Lumen (SL), 55 cm Length
5F Dual Lumen (DL), 55 cm Length
6F Triple Lumen (TL), 55 cm Length</td></tr>
</table></td></tr>
</table>

		5F Triple Lumen (TL) cm Length *PowerPICC Catheters:* 4F Single Lumen (SL), 55 cm Length 5F Dual Lumen (DL), 55 cm Length 5F Dual Lumen (DL), FT 55 cm Length, (4F between 5 and 30cm mark) 5F Triple Lumen (TL), 55 cm Length	
	Indications for use	The PowerPICC 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. The maximum infusion flow rate is 5 mL/second 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.	The PowerPICC SOLO catheter is 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 4 French or larger catheter. The maximum recommended infusion rate is 5 mL/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.
	Duration of use	Same	Short term (<30 days) or Long term (>30 days)
	Means of insertion	Same	Percutaneous
	Insertion site	Same	Peripheral
	Primary device materials	Same	*All Catheter Configurations Base Materials:* Shaft Tubing: Polyurethane Luer Connector: Polyurethane

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<tr><td></td><td>
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<tr><td></td><td></td><td>Extension Legs:
Polyurethane
Junction:
Polyurethane</td></tr>
<tr><td>Power injection maximum flow rate</td><td>Same</td><td>5 ml/sec</td></tr>
<tr><td>Sterility</td><td>Same</td><td>Ethylene Oxide</td></tr>
</table>

Reference devices used for specific technological characteristics include, K070996: 4 Fr Single Lumen PowerPICC Catheter, K053501: 6 Fr Triple Lumen PowerPICC Catheter, K051672: 5 Fr Dual Lumen PowerPICC Catheter. The technological differences and changes to the indications for use statement listed above were evaluated using industry consensus standards, and as defined in the Risk Assessment. These differences in technological characteristics between the subject and predicate devices do not raise new or different questions of safety or effectiveness.
</td></tr>
<tr><td>Performance Tests</td><td>
The following performance tests were conducted in determining substantial equivalence of the PowerPICC Catheter to the predicate devices.
<table>
<tr><th colspan="2">Reference Standard: ISO 10993-1:2009 – Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process</th></tr>
<tr><td>Biocompatibility Testing</td><td>Tests to confirm that the catheter is free from biological hazard per testing. A health-based risk assessment per ISO 10993-1 was performed for determining the acceptability of the material for the intended purpose.
Testing Performed includes:
Cytotoxicity
Sensitization
Irritation or Intracutaneous Reactivity
Acute Systemic Toxicity
Pyrogenicity
Subchronic Systemic Toxicity</td></tr>
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			• Genotoxicity • Chronic toxicity • Hemocompatibility • Implantation	
		Reference Standard: *ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements*		
		Leak Test	Test to confirm that the catheter assembly will not leak when the distal end of the catheter is occluded.	
		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.	
		Implantable Length	Test to measure useful length for catheters to ensure compliance with dimensional specification.	
		Extension Leg Length	Test to measure and confirm extension leg length compliance with dimensional specification.	
		Catheter Collapse Test	Test to measure the flow rate of aspiration and demonstrate that the catheter will not collapse under a vacuum.	
		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.	
		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.	
		Power Injection Conditioning	Test to confirm the catheter does not leak or burst as a result of power injections at maximum indicated flow rate.	
		Gravity Flow	Test to measure the gravity flow performance of a full-length catheter.	
		Luer to Extension Leg Tensile Test	Test to demonstrate the peak tensile force of each test piece exceeds the minimum peak tensile force.	

		Extension Leg to Trifurcation Tensile Test		
		Trifurcation to Shaft Tensile Test		
		Shaft Tensile Test		
		Reference Standard: *ASTM F640-12 – Standard Test Methods for Radiopacity of Plastics for Medical Use*		
		Radiopacity	Test to demonstrate catheter radio-detectability.	
		Reference Standard: *ISO 10555-3:2013 – Intravascular catheters – Sterile and single-use catheters – Part 3: Central venous catheters*		
		Tip Tensile	Test to demonstrate the peak tensile force of each test piece exceeds the minimum peak tensile force.	
		Reference Standard: FDA Guidance on *Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, 1995*		
		Shaft Tensile Test	Test to evaluate the maximum catheter strain and modulus at break.	
		Suture Wing Integrity Test	Test to measure the maximum force a catheter junction suture wing can withstand prior to break.	
		Priming Volume	Test to measure the volume required to prime a full-length catheter.	
		OD Swell	Test to confirm that the catheter does not swell beyond twice the size of the labeled OD during power injection.	
		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.	
		Guidewire Drag Test	Test to ensure that the guidewire used to place the catheter can be removed without difficulty.	

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<tr><td></td><td></td><td colspan="2">Reference Standard: ISO 80369-7: Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications</td><td></td></tr>
<tr><td></td><td></td><td>Luer Testing</td><td>Testing to ensure that luer connectors meet requirements for Stress Cracking, Resistance to Separation from Axial Load, Resistance to Separation from Unscrewing, and Resistance to Overriding.</td><td></td></tr>
<tr><td></td><td></td><td colspan="2">Reference Standard: USP 788 Particulate Matter in Injections</td><td></td></tr>
<tr><td></td><td></td><td>Particulate</td><td>Particulate matter is defined in the USP as extraneous, mobile, undissolved substances, other than gas bubbles, unintentionally present in a solution (or in/on a device).</td><td></td></tr>
<tr><td>Technological Comparison to Predicate and Reference Devices</td><td colspan="4">Technological characteristics of the subject PowerPICC Family (PowerPICC, PowerPICC SOLO, PowerPICC FT and PowerPICC Provena, PowerPICC Provena SOLO) Catheters are substantially equivalent with regard to the basic design and function of the predicate device, PowerPICC SOLO, K072230, Concurrence date November 18, 2008. It is known that the predicate and reference devices are made from grades of polyurethane typically used in catheters (and permitted, by 21 CFR §880.5970).</td></tr>
<tr><td>Summary of Substantial Equivalence</td><td colspan="4">Based on the risk management activities and testing, the subject PowerPICC Family Catheters have been demonstrated to be substantially equivalent to the cited predicate and reference devices.</td></tr>
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