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

December 14, 2016

C.R. Bard, Inc.
% Casey Coombs
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, Utah 84116

Re: K162900
Trade/Device Name: PowerMidline Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: PND
Dated: November 17, 2016
Received: November 18, 2016

Dear Mr. Coombs:

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, 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)*
K162900

Device Name
PowerMidline Catheter

Indications for Use *(Describe)*
The PowerMidline™ Catheters are indicated for short term access to the peripheral venous system for selected intravenous therapies, blood sampling, and power injection of contrast media. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The PowerMidline™ Catheters are suitable for use with power injectors.

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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BARD
ACCESS SYSTEMS

K162900

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:	Mr. Casey Coombs Regulatory Affairs Specialist
	Telephone Number:	(801) 522-5869
	Fax Number:	(801) 522-4969
	Date of Preparation:	November 27, 2016
Subject Device	Trade Name:	PowerMidline™ Catheter
	Common Name:	Intravascular Catheter
	Regulation Name:	Intravascular Catheter
	Product Code:	PND
	Regulation:	21 CFR § 880.5200
	Regulatory Class:	Class II
	Classification Panel:	General Hospital
Predicate Device	Predicate Trade Name:	PowerMidline™ Catheter
	Common Name:	Intravascular Catheter
	Regulation Name:	Intravascular Catheter
	Premarket Notification:	K153393 (cleared June 28, 2016)
	Manufacturer:	Bard Access Systems, Inc.
	Product Code:	PND
	Regulation:	21 CFR § 880.5200
	Regulatory Class:	Class II
	Classification Panel:	General Hospital
Reference Device	Reference Trade Name:	PowerPICC™ SV Catheter
	Common Name:	Peripherally Inserted Central Catheter (PICC)
	Regulation Name:	Percutaneous, implanted, long-term intravascular catheter
	Premarket Notification:	K102159 (cleared November 17, 2010)
	Manufacturer:	Bard Access Systems, Inc.
	Product Code:	LJS
	Regulation:	21 CFR § 880.5970
	Regulatory Class:	Class II
	Classification Panel:	General Hospital

Reference Device	Reference Trade Name: 6 F Triple Lumen PowerPICC™ Catheter Common Name: Peripherally Inserted Central Catheter (PICC) Regulation Name: Percutaneous, implanted, long-term intravascular catheter Premarket Notification: K053501 (cleared January 13, 2006) Manufacturer: Bard Access Systems, Inc. Product Code: LJS Regulation: 21 CFR § 880.5970 Regulatory Class: Class II Classification Panel: General Hospital
Device Description	The dual lumen PowerMidline™ catheters are a family of peripherally placed catheters made from radiopaque body-softening polyurethane materials. Each dual lumen PowerMidline™ catheter is designed with kink-resistant, reverse taper design. The dual lumen PowerMidline™ catheters are offered in a 4 F dual lumen (DL) and 5 F dual lumen (DL) configuration for reliable short term (less than 30 days) vascular access. These catheters are offered in 20 cm trimmable lengths. The dual lumen PowerMidline™ catheters are suitable for use with power injectors.
Intended Use	The PowerMidline™ Catheter is intended for short term peripheral access for selected intravenous therapies, blood sampling, and power injection of contrast media.
Indications For Use	The PowerMidline™ Catheters are indicated for short term access to the peripheral venous system for selected intravenous therapies, blood sampling, and power injection of contrast media. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The PowerMidline™ Catheters are suitable for use with power injectors.
Technological Characteristics	The technological characteristics of the subject PowerMidline™ Catheters are substantially equivalent with respect to basic design, materials and function to those of the cited predicate device. Key modifications made to the subject device when compared to the predicate device are as follows: • Modifications made to the number of lumens and extension legs to introduce the dual lumen configurations • Dimensional modifications made to introduce a 5 French size dual lumen catheter • Modifications made to the catheter junctions to accommodate the dual lumen configurations • Material modifications to the extension leg, luer hub, and catheter junction components to introduce the dual lumen configurations • Labeling modifications to reflect the dual lumen configurations The following table provides a comparison between the subject and predicate device.

	Subject and Predicate Device Comparison Table		
	Attribute	**Subject Device: Dual Lumen PowerMidline™ Catheter**	**Predicate Device: Single Lumen PowerMidline™ Catheter (K153393)**
Technological Characteristics	**Owner**	Same as predicate	Bard Access Systems, Inc.
	Classification	Same as predicate	PND - 21 CFR 880.5200 - Short-term - Intravascular Catheter
	510(k) Status	Subject of this Premarket Notification	K153393 - Clearance date June 28, 2016
	Indications for Use	Same as predicate	The PowerMidline™ Catheters are indicated for short term access to the peripheral venous system for selected intravenous therapies, blood sampling, and power injection of contrast media. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The PowerMidline™ Catheters are suitable for use with power injectors.
	Duration of Use	Same as predicate	Short term (<30 days)
	Means of Insertion	Same as predicate	Percutaneous, using Modified Seldinger Technique and guidewire
	Insertion Site	Same as predicate	Peripheral
	Tip Placement Location	Same as predicate	Peripheral venous system, with catheter tip terminating prior to the axilla
	Catheter Base Materials	Same as predicate	Shaft Tubing Polyurethane Catheter Junction Polyurethane Extension Leg Polyurethane Luer Hub Polyurethane

			Extension Leg Clamp Acetal Resin
Technological Characteristics	**Catheter Proximal Configuration**	Same as predicate	Luer Connection
	Catheter Distal Configuration	Same as predicate	Open Ended
	Catheter Dimensions	4 F DL x 20 cm usable length 5 F DL x 20 cm usable length	3 F SL x 20 cm usable length 4 F SL x 20 cm usable length
	Number, Shape of Lumens	Dual Lumen, two "D" shaped lumens	Single Lumen, round
	Depth Markings	Same as predicate	"0" depth indicator located 1 cm from catheter junction on reverse taper shaft tubing; catheter marked every 1 cm, with numeric indicators every 5 cm.
	Pre-inserted Stylet Configuration	Same as predicate	Stiffening stylet
	Power Injection Maximum Flow Rate	4 F DL = 4 mL/s 5 F DL = 7 mL/s	3 F SL = 3 mL/s 4 F SL = 7 mL/s
	Sterility	Same as predicate	Provided Sterile (EO)

Performance Tests

As part of Bard Access Systems, Inc.'s design controls, a risk analysis was conducted to assess the impact of the proposed device modifications. Based upon the results of the risk analysis, the necessary design control activities were identified to ensure that specified design requirements were met. 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. As required by the risk analysis, the following table identifies the performance tests completed on the subject device based upon the specific modifications made to develop the subject device. The table includes a description of testing completed and the standard(s) utilized with each test.

Testing Completed	ISO Standard / FDA Guidance / BAS Protocols Utilized
Test and Report Priming Volume	Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, March 16, 1995

Performance Tests

	BAS Internal Protocols/Procedures
Shaft Tensile	ISO 10555-1: 2013, Sterile, single-use intravascular catheters, Part 1: General requirements Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, March 16, 1995
Test and Report Modulus and Elongation Requirements	
Assembly Burst (Burst Pressure with Power Injection)	ISO 10555-1: 2013, Sterile, single-use intravascular catheters, Part 1: General requirements
Catheter Assembly Leak	
Catheter Assembly Tensile	
Test and Report Gravity Flow	
Device Dimensional Characterization	
Catheter Cyclic Kink	BAS Internal Protocols/Procedures
Tip Displacement During Power Injection	
Power Injection Testing	ISO 10555-1: 2013, Sterile, single-use intravascular catheters, Part 1: General requirements BAS Internal Protocols/Procedures

Per *ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process,* a biocompatibility evaluation was performed based upon the modifications made to develop the subject device.

Per design control requirements as specified in 21 CFR 820.30, the subject device met all predetermined acceptance criteria derived from the above listed tests and demonstrated substantial equivalence as compared to the cited predicate device.

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*.

Summary of Substantial Equivalence

The subject dual lumen PowerMidline™ Catheter has the same intended use and fundamental technological characteristics as the cited predicate device cleared under K153393. Based on the intended use, technological characteristics, and results of performance testing, the subject dual lumen PowerMidline™ Catheter is considered substantially equivalent to the cited predicate device.