May 13, 2022

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

Re: K213203
Trade/Device Name: Provena Midline Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: PND
Dated: April 13, 2022
Received: April 14, 2022

Dear Jeremy Kuyakana:

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,

Payal Patel
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K213203

Device Name
Provena™ Midline Catheter

Indications for Use *(Describe)*
The Provena™ Midline 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 Provena™ Midline 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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ACCESS SYSTEMS

K213203 - 510(k) Summary
21 CFR 807.92(a)

General Provisions	Submitter Name: Submitter Address: Contact Person: Telephone Number: Fax Number: Date of Preparation:	Bard Access Systems, Inc. 605 North 5600 West Salt Lake City, UT 84116 Jeremy Kuyakana Sr. Regulatory Affairs Specialist (801) 800-6474 (801) 565-2390 April 13, 2022
Subject Device	Trade Name: Common Name: Classification Name: Product Code: Regulation: Regulatory Class: Classification Panel:	Provena™ Midline Catheter (SL, DL) Intravascular Catheter Intravascular Catheter PND 21 CFR § 880.5200 Class II General Hospital
Predicate Device	Predicate Trade Name: Common Name: Classification Name: Premarket Notification: Manufacturer: Product Code: Regulation: Regulatory Class: Classification Panel:	PowerMidline™ Catheter (SL, DL) Intravascular Catheter Intravascular Catheter K162900 (Cleared 12/14/2016) Bard Access Systems, Inc. PND 21 CFR § 880.5200 Class II General Hospital
Device Description	Provena™ Midline Catheters are a family of peripherally placed catheters made from radiopaque body-softening polyurethane materials. Each Provena™ Midline Catheter is designed with kink-resistant, reverse taper design. Catheters are packaged in a tray with accessories for reliable short term (less than 30 days) vascular access. The Provena™ Midline Catheters are suitable for use with power-injectors.	
Intended Use	The Provena™ Midline Catheters are intended for short term peripheral access for selected intravenous therapies, blood sampling, and power injection of contrast media.	
Indications for Use	The Provena™ Midline 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 Provena™ Midline Catheters are suitable for use with power injectors.	

The technological characteristics of the subject Provena™ Midline Catheters are substantially equivalent with respect to basic design, materials and function to those of the cited predicate device. The differences are not critical and do not raise any new or different questions of safety and effectiveness.

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

1. Labelling
    - Modification made to the product name to introduce the Provena™ Midline Catheters. The new name is reflected in the indications for use as well as throughout the device labeling.

2. Materials
   Depending on subject catheter models:
    - Modifications made to the base materials, colorants, and inks

3. Technology
   Depending on subject catheter models:
    - Dimensional modifications

4. Performance
    - Modification to the power injection flow rate.

Technological Characteristics

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

Subject and Predicate Devices Comparison Table		
Attribute	**Subject Devices: Provena™ Midline Catheters**	**Predicate Devices: Dual Lumen PowerMidline™ Catheters**
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	K162900 – Dual Lumen PowerMidline™ Catheters (Clearance date December 14, 2016)
Commercial Name	Provena™ Midline Catheter	PowerMidline™ Catheter

Technological Characteristics	**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
	Number of Lumens	3F Single Lumen Provena™ Midline Catheter: 1 4F Dual Lumen Provena™ Midline Catheter: Same as predicate	4F Dual Lumen PowerMidline™ Catheter: 2
	Lumen Size	3F Single Lumen Provena™ Midline Catheter: 18 Ga 4F Dual Lumen Provena™ Midline Catheter: 18 Ga (both lumens)	4F Dual Lumen PowerMidline™ Catheter: 19 Ga (large power injectable lumen), 21 Ga (small lumen)
	Lumen Geometry	3F Single Lumen Provena™ Midline Catheter: Circular lumen 4F Dual Lumen Provena™ Midline Catheter: Two identical D shaped lumens	4F Dual Lumen PowerMidline™ Catheter: One large D shaped lumen and one small D shaped lumen
	Catheter Base Materials	*Catheter Base Materials* <u>Shafts Tubing</u> Same as predicate <u>Catheter Junctions</u> Same as predicate <u>Extension Legs</u> Same as predicate <u>Luer Hubs</u> Same as predicate <u>Extension Leg Clamps</u> Same as predicate	*Catheter Base Materials* <u>Shafts Tubing</u> Polyurethane <u>Catheter Junctions</u> Polyurethane <u>Extension Legs</u> Polyurethane <u>Luer Hubs</u> Polyurethane <u>Extension Leg Clamps</u> Acetal Resin

Catheter Proximal Configuration	Same as predicate	Luer Connection
Catheter Distal Configuration	Same as predicate	Open Ended
Catheter Dimensions	3F Single Lumen Provena™ Midline Catheter: 3 French Single lumen x 20 cm usable length	4F Dual Lumen PowerMidline™ Catheter: 4 French Dual lumen x 20 cm usable length
	4F Dual Lumen Provena™ Midline Catheter: Same as predicate	
Power Injection Maximum Flow Rate (mL/sec)	3F Single Lumen Provena™ Midline Catheter: 6	4F Dual Lumen PowerMidline™ Catheter: 3
	4F Dual Lumen Provena™ Midline Catheter: 6	
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.
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, design control activities were identified to ensure that specified design requirements were met. The performance tests completed on the subject devices were limited to those tests required to support a determination of substantial equivalence to the predicate devices. In addition, when technological characteristics between the subject and predicate devices were found to be identical, results of the performance testing conducted on the predicate devices were applied to the subject devices. As required by the risk analysis, the following table identifies the performance tests completed on the subject devices based upon the specific modifications made to develop the subject devices. The table below includes a description of testing completed and the standard(s) followed for each test.

Testing Completed	Standard(s) Followed
Priming Volume	Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, March 16, 1995
Particulate Matter Testing	USP 788
Assembly Burst (Burst Pressure with Power Injection)	ISO 10555-1: 2013, Sterile, single-use intravascular catheters, Part 1: General requirements
Catheter Assembly Leak	

Performance Tests

Catheter Assembly Tensile	ISO 10555-1: 2013, Sterile, single-use intravascular catheters, Part 1: General requirements
Gravity Flow	
Device Dimensional Characterization	
Power Injection Testing	ISO 10555-1: 2013, Sterile, single-use intravascular catheters, Part 1: General requirements

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 device modifications and the device classification of the subject devices.

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

Technological Comparison to Predicate Device

Technological characteristics of the subjects Provena™ Midline Catheters are substantially equivalent with regard to the basic design and function of the predicate device: Dual Lumen PowerMidline™ Catheters (K162900).

The size, number, and geometry of the lumens in the subject devices, as well as the flow rates differ from the predicate devices. However, these differences do not alter the intended use of the subject devices, and do not raise any new or different questions regarding safety or effectiveness when compared to the predicate devices.

Summary of Substantial Equivalence

The subject Provena Midline Catheters have the same intended use and fundamental technological characteristics as the cited predicate device cleared under K162900. Based on the intended use, technological characteristics, and results of performance testing, the subject Provena™ Midline Catheters are considered substantially equivalent to the cited predicate device.