DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 1, 2017

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

Re: K170158
Trade/Device Name: PowerGlide ST™ Midline Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: PND
Dated: May 4, 2017
Received: May 5, 2017

Dear Mr. Jacob Lee:

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)*
K170158

Device Name
PowerGlide ST Midline Catheter

Indications for Use *(Describe)*

The PowerGlide ST Midline Catheter is inserted into a patient's vascular system for short term use to sample blood or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The PowerGlide ST Midline Catheter is 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

K170158

510(k) Summary
21 CFR 807.92(a)

General Provisions	Submitter Name: Address: Contact Person: Telephone Number: Fax Number: Date of Preparation:	Bard Access Systems, Inc. 605 North 5600 West Salt Lake City, UT 84116 Jacob Lee Regulatory Affairs Specialist (801) 522-5823 (801) 522-4969 May 26, 2017
Subject Device	Trade Name: Common Name: Regulation Name: Product Code: Regulation: Regulatory Class: Classification Panel:	PowerGlide ST™ Midline Catheter Intravascular Catheter Intravascular Catheter PND 21 CFR § 880.5200 II General Hospital
Predicate Device	Predicate Trade Name: Premarket Notification: Manufacturer: Common Name: Regulation Name: Product Code: Regulation: Regulatory Class Classification Panel:	PowerGlide Pro™ Midline Catheter K162377 (cleared September 22, 2016) Bard Access Systems, Inc. Intravascular Catheter Intravascular Catheter FOZ 21 CFR § 880.5200 II General Hospital
Device Description	Bard Access Systems, Inc.'s PowerGlide ST™ Midline Catheter is a sterile, single use device designed to provide access to the patient's vascular system. The device is intended for short term use (<30 days) to sample blood and administer fluids intravenously. The subject device consists of a single lumen, radiopaque, body softening polyurethane catheter rated for power injection, and a dilator (when applicable). Additional procedural kit accessories (e.g. introducer needle and guidewire) are included to facilitate catheter placement. The PowerGlide ST™ Midline Catheter is offered in 18, 20, and 22 gauge sizes. The 18 and 20 gauge devices are offered in 8 cm or 10 cm lengths with an integrated dilator. The 22 gauge device is offered in only an 8 cm length and does not include a dilator.	
Intended Use	The PowerGlide ST™ Midline Catheter is intended to be inserted in the patient's vascular system for short term use to sample blood or administer fluids intravenously.	

Indications For Use

The PowerGlide ST™ Midline Catheter is inserted into a patient's vascular system for short term use to sample blood or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The PowerGlide ST™ Midline Catheter is suitable for use with power injectors.

Technological Characteristics

The technological characteristics of the subject PowerGlide ST™ Midline Catheters are substantially equivalent with respect to basic design and function to those of the predicate PowerGlide Pro™ Midline Catheter. The catheter assemblies (catheter shaft, luer hub and strain relief) used in both the subject and predicate devices are identical. The differences between the subject and predicate devices are not critical to the intended use of the device and do not impact the substantial equivalence determination. The key differences between the subject and predicate device include the following:

- The subject device catheter insertion procedure uses the Seldinger Technique (ST) and is different than the all in one catheter insertion technique of the predicate device. However, both the subject and predicate devices are inserted into the vasculature over a guidewire.
- The subject device does not include the predicate device housing or insertion mechanism components. The predicate device housing and insertion mechanism components are required to facilitate the all in one catheter placement technique. Rather, the subject device will be accompanied by legally marketed procedural kit components (e.g. introducer needle and guidewire) that are necessary when inserting the subject device using the ST.
- The subject device includes a dilator assembly (dilator shaft, hub and locking collar) that is integrated into the catheter assembly to assist catheter insertion using the ST. The predicate device catheter is preloaded over an introducer needle and does not include a dilator component.

The following table provides a comparison of the technological characteristics between the subject and predicate devices in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence.

Subject and Predicate Device Comparison Table

Attribute	Subject Device: PowerGlide ST™ Midline Catheter	Predicate Device: PowerGlide Pro™ Midline Catheter (K162377)
Owner	Same as predicate	Bard Access Systems, Inc.
Classification	PND - 21 CFR 880.5200 - Intravascular Catheter	FOZ - 21 CFR 880.5200 - Intravascular Catheter
510(k) Status	Subject of this Premarket Notification	K162377 - Clearance date September 22, 2016

Indications for Use	Same as the predicate with the exception of the subject device trade name and the removal of "(<30 days)": The PowerGlide ST™ Midline Catheter is inserted into a patient's vascular system for short term use to sample blood or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The PowerGlide ST™ Midline Catheter is suitable for use with power injectors.	The PowerGlide Pro™ Midline Catheter is inserted into a patient's vascular system for short-term use (<30 days) to sample blood or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of the procedure. The PowerGlide Pro™ Midline Catheter is suitable for use with power injectors.
Commercial Name	PowerGlide ST™ Midline Catheter	PowerGlide Pro™ Midline Catheter
Catheter Dimensions	Same as predicate	Length: 8 and 10 cm Diameter: 18, 20, 22* Gauge *22Ga is 8 cm length only
Duration of Use	Same as predicate	Short term
Primary Device Components	• Catheter • Dilator (18 & 20 Ga only)	• Catheter • Needle • Guidewire
Means of Insertion	Same as predicate	Percutaneous, Over a Guidewire
Insertion Site	Same as predicate	Peripheral
Primary Device Materials	**Catheter Base Materials** • Shaft Tubing: Same as predicate • Luer Hub: Same as predicate • Catheter Tip: Same as predicate **Dilator** • Hub: Isoplast Polyurethane • Locking Collar: Polycarbonate • Shaft: Isoplast Polyurethane	**Catheter Base Materials** • Shaft Tubing: Polyurethane • Luer Hub: Isoplast Polyurethane • Catheter Tip: Isoplast Polyurethane **Needle** • Stainless Steel **Guidewire** • Nitinol
Catheter Proximal Configuration	Same as predicate	Luer Connection
Catheter Distal Configuration	Same as predicate	Open Ended

Number of Lumens	Same as predicate	Single Lumen
Power Injection Maximum Flow Rate	Same as predicate	18 Gauge = 7 mL/s max 20 Gauge = 5 mL/s max 22 Gauge = 2 mL/s max
Sterility	Same as predicate	Provided Sterile (EO)
Packaging Configurations	Same as predicate	Basic Configuration Full Configuration Max Configuration

Performance Tests

Verification and validation tests have been performed in accordance with Design Controls as per 21 CFR § 820.30. 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, including a test description and applicable standard associated with each test.

Subject Device Verification Testing		
Performance Tests	**Test Description**	**Standard Utilized**
Dilator Outer Diameter	Test to confirm that the OD of the dilator is within design specifications.	Bard internal standards and procedures
Dilator Effective Length	Test to confirm that the length of the dilator is within design specifications.	*BS EN ISO 11070:2014 – Sterile single-use intravascular introducers, dilators, and guidewires*
Dilator Luer Connector	Tests to confirm that all 6% luer fittings and connectors comply with ISO 594-1 and 594-2	*ISO 594-1:1986 - Conical fittings with 6% luer taper for syringes, needles and certain other medical equipment - Part 1: General Requirements* *ISO 594-2: 1998 - Conical fittings with 6% luer taper for syringes, needles and certain other medical equipment - Part 2: Lock Fittings*
Catheter/Dilator Tip Adhesion Break Force	Test to demonstrate the force required to remove the dilator from the catheter when the locking collar has been removed.	Bard internal standards and procedures
Dilator Assembly Tensile	Test to verify that the dilator assembly does not fail in tension with forces below the predetermined	*BS EN ISO 11070:2014 – Sterile single-use intravascular introducers, dilators, and guidewires*

	acceptance criteria.	
Catheter/Dilator Assembly Burst Pressure	Test to verify that the burst pressure is greater than maximum use pressure.	*ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements*

Performance Tests

A biocompatibility evaluation was conducted on 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 the evaluation, the biological tests in the table below were conducted.

Biological Test	Test Standard
Cytotoxicity	*ISO 10993-5 (2009)*
Sensitization	*ISO 10993-10 (2010)*
Intracutaneous Reactivity	*ISO 10993-10 (2010)*
Acute Systemic Toxicity	*ISO 10993-11 (2006)*
Pyrogenicity	*ISO 10993-11 (2006)*
Hemocompatibility	*ISO 10993-4 (2002, amended 2006)*
Genotoxicity	*ISO 10993-3 (2014) ISO/TR 10993-33 (2015)*
Sterilization Residuals	*ISO 10993-7*

The subject device met all predetermined acceptance criteria derived from the above listed tests and demonstrated substantially equivalent performance 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 PowerGlide ST™ Midline Catheter has the same intended use as the cited predicate device. The catheter assemblies utilized in both the subject and predicate devices are identical; therefore, the technological characteristics are the same with respect to the catheter assembly. The dilator assembly component of the subject device introduces different technological characteristics from the cited predicate device. The results of performance and biological tests conducted on the subject PowerGlide ST™ Midline Catheter met all predetermined acceptance criteria and demonstrated that the differences in technological characteristics do not impact the substantial equivalence determination. Therefore, the proposed subject PowerGlide ST™ Midline Catheter is considered substantially equivalent to the cited predicate device.