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

September 22, 2016

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

Re: K162377
Trade/Device Name: PowerGlide Pro™ Midline Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: August 22, 2016
Received: August 24, 2016

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" (21CFR 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

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)*

K162377

Device Name
PowerGlide Pro Midline Catheter

Indications for Use *(Describe)*

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.

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

K162377

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 Jacob Lee Regulatory Affairs Specialist (801) 522-5823 (801) 522-5425 September 14, 2016
Subject Device	Trade Name: Common Name: Regulation Name: Product Code: Regulation: Regulatory Class: Classification Panel:	PowerGlide Pro™ Midline Catheter Intravascular Catheter Intravascular Catheter FOZ 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 K153280 (cleared June 2, 2016) Bard Access Systems, Inc. Intravascular Catheter Intravascular Catheter FOZ 21 CFR § 880.5200 II General Hospital
Device Description	The PowerGlide Pro™ 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, and employs an identical placement technique to the cited predicate device. The subject device consists of an introducer needle with a passive safety mechanism, guidewire, and single lumen catheter rated for power injection. The subject PowerGlide Pro™ Midline Catheter features a catheter with a reinforced tip to support patency of the catheter during aspiration or blood draw. The PowerGlide Pro™ 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. The 22 gauge device is offered in only an 8 cm length.	
Intended Use	The PowerGlide Pro™ Midline Catheter is intended to be inserted in the patient's vascular system for short term use (less than 30 days) to sample blood or administer fluids intravenously.	

Indications For Use

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.

Technological Characteristics

The technological characteristics of the subject PowerGlide Pro™ Midline Catheter are substantially equivalent with respect to basic design, materials and function to those of the cited predicate device. The differences are not critical to the intended use of the device 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:

- Reinforced catheter tip – Integration of material to the inner diameter of the catheter tip.
- Labeling modifications – The content description of the unit label will be revised to identify the catheter with reinforced tip. All other types of device labeling (case labels, IFU, inserts, etc.) will remain the same as the predicate device.

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

Subject and Predicate Device Comparison Table		
Attribute	**Subject Device: PowerGlide Pro™ Midline Catheter**	**Predicate Device: PowerGlide Pro™ Midline Catheter (K153280)**
Owner	Same as predicate	Bard Access Systems, Inc.
Classification	Same as predicate	FOZ - 21 CFR 880.5200 - Short-term - Intravascular Catheter
510(k) Status	Subject of this Premarket Notification	K153280 - Clearance date June 2, 2016
Indications for Use	Same as predicate	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	Same as predicate	PowerGlide Pro™ Midline Catheter

Technological Characteristics

Subject and Predicate Device Comparison Table		
Attribute	**Subject Device: PowerGlide Pro™ Midline Catheter**	**Predicate Device: PowerGlide Pro™ Midline Catheter (K153280)**
Catheter Dimensions	Same as predicate	Length: 8 and 10 cm Diameter: 18, 20, 22* Gauge *22Ga is 8cm length only
Duration of Use	Same as predicate	Short term (<30 days)
Primary Device Components	Same as predicate	• 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 (Inner Diameter): Isoplast Polyurethane (same as Luer Hub) Needle • Same as predicate Guidewire • Same as predicate	Catheter Base Materials: • Shaft Tubing: Polyurethane • Luer Hub: 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

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 modification to the catheter tip, including a test description and applicable standard associated with each test.

Performance Tests	Test Description / Standard Utilized
Catheter Tip Adhesion Break Force	Test to demonstrate the force required to push the catheter off the needle after potential adhesion due to conditioning. The force required shall be less than or equal to the predicate device. • Bard internal standards and procedures
Catheter Swelling OD	Test to confirm that the catheter does not swell beyond twice the size of the labeled OD during power injection. • Bard internal standards and procedures
Catheter Collapse	Test to measure the flow rate of aspiration and demonstrate that the catheter tip will not collapse under a vacuum. • Bard internal standards and procedures and FDA guidance, *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters (March 16, 1995)*
Tip Location During and After Power Injection	Test to confirm that the catheter tip remains in the same orientation during power injection (tip pointing in direction of venous flow) and does not kink following power injection when conducted at the maximum indicated flow rate. • Bard internal standards and procedures
Reinforced Tip Flexural Fatigue (Cyclic Kinking and Burst Test)	Burst pressure test to confirm the reinforced tip material will not separate from the catheter shaft under maximum use pressure conditions following cyclical kink conditioning of the catheter tip. The burst pressure must be greater than maximum use pressure when the tip is occluded. • Bard internal standards and procedures and *ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements*
Reinforced Tip Separation Strength	Burst pressure test to confirm the reinforced tip material will not separate from the catheter shaft under maximum use pressure conditions. The burst pressure must be greater than maximum use pressure when the tip is occluded. • *ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements*

Performance Tests	A biocompatibility evaluation was conducted based upon the specific modification to 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 this evaluation the following hemocompatibility tests were conducted per *ISO 10993-4:2002*, *Biological Evaluation of Medical Devices – Part 4: Selection of tests for interaction with blood*: • Hemolysis • Coagulation (UPTT & PT) • Compliment Activation Per design control requirements as specified in 21 CFR 820.30, the subject device met all predetermined acceptance criteria derived from the above listed verification 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 PowerGlide Pro™ Midline Catheter has the same intended use and fundamental technological characteristics as the cited predicate device cleared under K153280. Based on the intended use, technological characteristics, and results of performance testing, the subject PowerGlide Pro™ Midline Catheter is considered substantially equivalent to the cited predicate device.