



Food and Drug Administration
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June 2, 2016

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

Re: K153280
Trade/Device Name: PowerGlide Pro™ Midline Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: April 29, 2016
Received: May 2, 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

 Tina Kiang -
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for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153280

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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K153280

**510(k) Summary
21 CFR 807.92(a)**

General Provisions	Submitter Name:	Bard Access Systems, Inc.
	Address:	605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Mr. Casey Coombs
	Telephone Number:	(801) 522-5869
	Fax Number:	(801) 522-5425
Date of Preparation:	1 June 2016	

Subject Device	Trade Name:	PowerGlide Pro™ Midline Catheter
	Common Name:	Intravascular Catheter
	Classification Name:	Intravascular Catheter
	Product Code:	FOZ
	Regulation:	21 CFR § 880.5200

Predicate Device	Predicate Trade Name:	PowerGlide™ Midline Catheter
	Classification Name:	Intravascular Catheter
	Premarket Notification:	K133856
	Manufacturer:	Bard Access Systems, Inc.

Reference Device	Reference Trade Name:	PowerGlide™ Midline Catheter
	Classification Name:	Intravascular Catheter
	Premarket Notification:	K121073
	Manufacturer:	Bard Access Systems, Inc.

Device Description	<p>Bard Access Systems, Inc.'s 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 a placement technique similar 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 PowerGlide Pro™ Midline Catheter features device housings and insertion mechanisms that are different from the predicate device.</p>
	<p>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.</p>

Intended Use	<p>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.</p>
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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 of the subject PowerGlide Pro™ Midline Catheter are substantially equivalent with respect to basic design and function to those of the predicate PowerGlide™ Midline Catheters. The differences are not critical to the intended use of the device and do not raise any new questions regarding safety or effectiveness.

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

Technological Characteristics

Subject and Predicate/Reference Device Comparison Table			
Attribute	Subject Device – PowerGlide Pro™ Midline Catheter	Predicate Device – PowerGlide™ Midline Catheter (K133856)	Reference Device – PowerGlide™ Midline Catheter (K121073)
Device Class	Same	FOZ 21 CFR 880.5200 Short-term Intravascular Catheter	FOZ 21 CFR 880.5200 Short-term Intravascular Catheter
Indications for Use	Same – with exception of trade name	The PowerGlide™ 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™ Midline Catheter is suitable for use with power injectors.	The PowerGlide™ 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™ Midline Catheter is suitable for use with power injectors.
Duration of Use	Same	Short term (<30 days)	Short term (<30 days)
Primary Device Components	Same	Needle Guidewire Catheter	Needle Guidewire Catheter
Means of Insertion	Same	Percutaneous, over a guidewire	Percutaneous, over a guidewire
Insertion Site	Same	Peripheral	Peripheral

Technological Characteristics

Catheter, Needle, Guidewire Materials	<p><i>Catheter Base Materials</i></p> <ul style="list-style-type: none"> • <u>Shaft Tubing:</u> Same • <u>Luer Hub:</u> Same <p><i>Needle</i></p> <ul style="list-style-type: none"> • Same <p><i>Guidewire</i></p> <ul style="list-style-type: none"> • Same as Predicate (K133856) 	<p><i>Catheter Base Materials</i></p> <ul style="list-style-type: none"> • <u>Shaft Tubing:</u> Polyurethane • <u>Luer Hub:</u> Polyurethane <p><i>Needle</i></p> <ul style="list-style-type: none"> • Stainless Steel <p><i>Guidewire</i></p> <ul style="list-style-type: none"> • Nitinol 	<p><i>Catheter Base Materials</i></p> <ul style="list-style-type: none"> • <u>Shaft Tubing:</u> Polyurethane • <u>Luer Hub:</u> Polyurethane <p><i>Needle</i></p> <ul style="list-style-type: none"> • Stainless Steel <p><i>Guidewire</i></p> <ul style="list-style-type: none"> • Stainless Steel
Catheter Proximal Configuration	Same	Luer Connection	Luer Connection
Catheter Distal Configuration	Same	Open Ended	Open Ended
Catheter Dimensions	<p><u>18/20/22 gauge catheter</u> Same as predicate/reference device based on gauge size</p>	<p><u>18 gauge catheter</u></p> <ul style="list-style-type: none"> • Length: 8 and 10 cm • Diameter: 18 gauge <p><u>22 gauge catheter</u></p> <ul style="list-style-type: none"> • Length: 8 cm • Diameter: 22 gauge 	<p><u>20 gauge catheter</u></p> <ul style="list-style-type: none"> • Length: 8 and 10 cm • Diameter: 20 gauge
Number of Lumens	Same	Single Lumen	Single Lumen
Catheter Labeling	<p><u>18/20/22 gauge catheter</u> Same as predicate/reference device based on gauge size</p>	<p>The luer hub is labeled with:</p> <p><u>18 gauge catheter</u></p> <ul style="list-style-type: none"> • Bard • PowerGlide • 7 mL/s max • 10 cm or 8 cm <p><u>22 gauge catheter</u></p> <ul style="list-style-type: none"> • Bard • PowerGlide • 2 mL/s max • 8 cm 	<p>The luer hub is labeled with:</p> <p><u>20 gauge catheter</u></p> <ul style="list-style-type: none"> • Bard • PowerGlide • 5 mL/s max • 10 cm or 8 cm
Power Injection Maximum Flow Rate	Same as predicate/reference device based on gauge size	18 gauge catheter = 7 mL/s 22 gauge catheter = 2 mL/s	20 gauge catheter = 5 mL/s

Technological Characteristics

Needle Dimensions	Same as predicate/reference device based on catheter gauge size	18 gauge device = Needle OD: 21 gauge 22 gauge device = Needle OD: 24 gauge	20 gauge device = Needle OD: 22 gauge
Needle Bevel	Same	B Bevel	B Bevel
Needle-shield feature	Same	The PowerGlide® Midline Catheter includes a passive safety guard mechanism. The safety guard locks over the needle tip as the needle is withdrawn from the vein.	The PowerGlide® Midline Catheter includes a passive safety guard mechanism. The safety guard locks over the needle tip as the needle is withdrawn from the vein.
Guidewire OD	Same as predicate/reference device based on catheter gauge size	18 gauge device = Guidewire OD: 0.018" 22 gauge device = Guidewire OD: 0.010"	20 gauge device = Guidewire OD: 0.014"
Guidewire Tip Type	Same	Soft Tip	Soft Tip
Sterility	Same	Provided Sterile	Provided Sterile

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. Additionally, when technological characteristics between the subject and predicate device were found to be identical, results of 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 the standards associated to each test.

Performance Tests

Performance Tests Completed	ISO Standard Utilized
Burst Pressure Post Power Injection	<i>ISO 10555 - 1: 2013, Sterile, single use intravascular catheters, Part 1: General requirements</i>
Burst Pressure Without Power Injection	
Effective Needle Length	<i>ISO 11070: 2014, Sterile, single use intravascular catheter introducer Coronary and Cerebrovascular Guidewire Guidance, January 1995</i>
Effective Guidewire Length	
Needle to Hub Tensile Strength	
Guidewire Bond Tensile Strength	

The following biological tests were also performed on the subject device:

- Cytotoxicity - *ISO 10993-5: 2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- Sensitization/Irritation - *ISO 10993-10: 2010, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*

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**

Based on the intended use, technological characteristics, and performance testing, the subject PowerGlide Pro™ Midline Catheter met the requirements that are considered sufficient for its intended use and is therefore substantially equivalent to the predicate device cited.
