July 29, 2024

Becton, Dickinson and Company (Bard Access Systems, Inc.)
Abigail Ryder
Senior Regulatory Affairs Specialist
605 S 5600 W
Salt Lake City, Utah 84116

Re: K240359
Trade/Device Name: PowerGlide Pro™ Midline Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: June 26, 2024
Received: June 28, 2024

Dear Abigail Ryder:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

David Wolloscheck

David Wolloscheck, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240359

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 adult and pediatric patients, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K240359. 510(k) Summary

General Provisions	Submitter Name:	Bard Access Systems, Inc. (BD)
	Submitter Address:	605 North 5600 West Salt Lake City, Utah 84116
	Contact Person:	Abigail Ryder Senior Regulatory Affairs Specialist
	Telephone Number:	801.522.5000
	Date of Preparation:	July 29th, 2024
Subject Device:	Trade Name:	PowerGlide Pro™ Midline Catheter
	Common Name:	Intravascular Catheter
	Classification Name:	catheter, intravascular, therapeutic, short-term less than 30 days
	Class:	Class II
	Regulation Number:	880.5200
	Product Code:	FOZ
	Classification Panel:	General Hospital
Predicate Device	Trade Name:	PowerGlide Pro™ Midline Catheter
	Common Name	Intravascular Catheter
	Classification Name:	catheter, intravascular, therapeutic, short-term less than 30 days
	Class:	Class II
	Regulation Number:	880.5200
	Premarket Notification Number:	K162377
Device Description	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. The device consists of an introducer needle with a passive safety mechanism, guidewire, and single lumen, **radiopaque, body-softening polyurethane** catheter rated for power injection.	

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 **adult and pediatric patients,** 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

Technological characteristics of the subject PowerGlide Pro™ Midline Catheter are substantially equivalent with respect to design and function to those of the cited predicate device.

The key modification made to the subject device when compared to the predicate device is the mention of The PowerGlide™ Pro Midline catheters may be considered for patients with difficult intravascular access (DIVA) as clinically indicated; addition of mention of use in adult and pediatric populations in the indications for use; and removal of a contraindication. As a result, the Instructions for Use (IFU) were updated to reflect the modification, the indications for use were updated, and the contraindication of the device for use in patients with infection was also removed. There are no other differences between the subject and predicate devices. The following table provides a comparison between the subject and predicate device:

Attribute	Predicate Device PowerGlide Pro™ Midline Catheter (K162377)	Subject Device PowerGlide Pro™Midline Catheter	Comparison
Owner	Bard Access Systems, Inc.	Bard Access Systems, Inc.	Same
Classification	Bard Access Systems, Inc.	Bard Access Systems, Inc.	Same
510(k) Status	K162377	Subject of this Premarket Notification	-
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 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 **adult and pediatric patients,** 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.	Added mention of adult and pediatric patients. There is no effect on device safety or effectiveness or any significant change in risk. Addressed in Risk Assessment RA82172.

		the procedure. The PowerGlide Pro™ Midline Catheter is suitable for use with power injectors.		
	Device Description	Bard Access Systems, Inc.'s PowerGlide Pro™ Midline Catheter is a single use, sterile **intravascular catheters** 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 device consists of an introducer needle with a passive safety mechanism, guidewire, and single lumen catheter rated for power injection.	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. The device consists of an introducer needle with a passive safety mechanism, guidewire, and single lumen, **radiopaque, body-softening polyurethane** catheter rated for power injection. ***Midline catheters, including the PowerGlide Pro, may be considered in patients with difficult IV access as clinically indicated.***	The Device Description is being updated with minor clarifications based on existing product and existing materials, as well as mentioning that Midline catheters including PowerGlide Pro can be considered in patients with difficult IV access as appropriate. There is no change to the device itself. The mention of patients with difficult IV access does not raise new questions of safety and effectiveness and does not introduce any new or significantly modified risks.
	Contraindications	The device is contraindicated whenever: • **The presence of device-related infection, bacteremia, or septicemia is known or suspected.**	The device is contraindicated whenever: • The patient's body size is insufficient to accommodate the size of the implanted device.	Removal of the contraindication does not raise new questions of safety or effectiveness and there are no new or

		• The patient's body size is insufficient to accommodate the size of the implanted device. • The patient is known or is suspected to be allergic to materials contained in the device. • Local tissue factors and/or past treatment will prevent proper device stabilization and/or access.	• The patient is known or is suspected to be allergic to materials contained in the device. • Local tissue factors and/or past treatment will prevent proper device stabilization and/or access.	significantly modified risks.
	Warnings	N/A	**Discontinue use of the PowerGlide Pro Midline Catheter device if it is known to be the source of infection. Otherwise, use clinical judgement regarding device removal.**	Included warning based on existing risks for PowerGlide Pro™, being added to clarify clinician judgement on device removal if identified or suspected as the source of infection. The addition does not raise new questions of safety or effectiveness and does not introduce any new or modified risks.
	Precautions	N/A	**Select the most appropriate vascular access device based on the necessary and anticipated therapies, patient history and overall vascular health which may include difficult intravascular access, along with the available resources to care for the vascular access device.**	Precaution is being added as a clarification for clinicians based on the device's existing risks, especially for when considering for use in patients with difficult intravascular access. The addition of

				this precaution does not raise new questions of safety or effectiveness and does not introduce any new or modified risks.
	Commercial Name	PowerGlide Pro™ Intravascular Catheter	PowerGlide Pro™ Intravascular Catheter	Same
	Catheter Dimensions	Length: 8 and 10 cm Diameter: 18, 20, 22* Gauge *22Ga is 8cm length only	Length: 8 and 10 cm Diameter: 18, 20, 22* Gauge *22Ga is 8cm length only	Same
	Durations of Use	Short term (<30 days)	Short term (<30 days)	Same
	Primary Device Components	Needle Guidewire Catheter	Needle Guidewire Catheter	Same
	Means of Insertion	Percutaneous, over a guidewire	Percutaneous, over a guidewire	Same
	Insertion Site	Peripheral	Peripheral	Same
	Primary Device Components and Materials	**Catheter** Shaft: Polyether Polyurethane with Barium Sulfate Lubricant Silicone Catheter Tip Polyurethane, Colorant Luer Hub: Polyurethane, Colorant, Ink Strain Relief: Polyether Polyurethane,	**Catheter** Shaft: Polyether Polyurethane with Barium Sulfate Lubricant Silicone Catheter Tip Polyurethane, Colorant Luer Hub: Polyurethane, Colorant, Ink Strain Relief: Polyether Polyurethane, Barium	Same

		Barium Sulfate, Colorants **Needle** Shaft: Stainless Steel Lubricant: Silicone Hub: Polycarbonate, Colorant, Adhesive **Needle Safety** Housing: Polycarbonate Internal Safety Mechanism: Silicone, Stainless Steel **Guidewire** Nitinol **Guidewire "Push Off"/Guidewire Coupler** Acetal Resin, PTFE Lubricant, Colorant **Catheter Handle (Wings)** Base Material (all sizes): Polystyrene, Colorants **Blood Control Mechanism** Biomedical Grade Silicone **Housing (Top and Bottom)** Top Housing: Polycarbonate, White Colorant Bottom Housing: Polycarbonate	Sulfate, Colorants **Needle** Shaft: Stainless Steel Lubricant: Silicone Hub: Polycarbonate, Colorant, Adhesive **Needle Safety** Housing: Polycarbonate Internal Safety Mechanism: Silicone, Stainless Steel **Guidewire** Nitinol **Guidewire "Push Off"/Guidewire Coupler** Acetal Resin, PTFE Lubricant, Colorant **Catheter Handle (Wings)** Base Material (all sizes): Polystyrene, Colorants **Blood Control Mechanism** Biomedical Grade Silicone **Housing (Top and Bottom)** Top Housing: Polycarbonate, White Colorant Bottom Housing: Polycarbonate	

		Needle/Catheter Protective Cover Polypropylene	**Needle/Catheter Protective Cover** Polypropylene	
	Catheter Proximal Configuration	Luer Connection	Luer Connection	Same
	Catheter Distal Configuration	Open Ended	Open Ended	Same
	Number of Lumens	Single Lumen	Single Lumen	Same
	Power Injection Maximum Flow Rate	18 Gauge = 7 mL/s max 20 Gauge = 5 mL/s max 22 Gauge = 2 mL/s max	18 Gauge = 7 mL/s max 20 Gauge = 5 mL/s max 22 Gauge = 2 mL/s max	Same
	Sterility	Provided Sterile	Provided Sterile	Same
	Packaging Configuration	Basic Configuration Intermediate Configuration Max Barrier Configuration	Basic Configuration Intermediate Configuration Max Barrier Configuration	Same
	Intended Use Environment	The typical environment for the placement, access, and use of PowerGlide Pro™ Midline Catheters may include: • Imaging Centers • Infusion Centers • Hospital/Hospital Ward • Physician's Office/Clinic • Home Health Care • ICU/Critical Care Ward • Emergency Department • OR	Same	Same

Performance Tests	As part of Bard Access Systems, Inc.'s design controls, a risk analysis was conducted to assess the impact of the proposed subject device labeling modifications. The results of the risk analysis determined that no verification or validation activities were required because the subject device modifications to the Indications for use and resulting modifications to the instructions for use and labeling do not include any changes to the design, materials, performance, or risk profile of the cited predicate device. Therefore, it is not necessary to conduct additional performance tests including verification and validation.
Summary of Substantial Equivalence	The modification to the indications for use and resulting modifications to the product instructions for use and labeling has no impact on the intended use, technological characteristics, or risk profile of the subject device because there are no changes to the design or performance of the predicate device. Therefore, the subject PowerGlide Pro™ Midline Catheter is substantially equivalent to the predicate PowerGlide Pro™ Midline Catheter.