K133856

JAN 16 2014

BARD
ACCESS SYSTEMS

510(k) Summary
21 CFR 807.92

General Provisions	Submitter Name:	Bard Access Systems, Inc.
	Submitter Address:	605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Casey Coombs Regulatory Affairs Specialist
	Telephone Number:	(801) 522-5869
	Fax Number:	(801) 522-5425
	Date of Preparation:	December 17, 2013
Subject Device	Trade Name:	PowerGlide® Midline Catheter
	Common Name:	Intravascular Catheter
	Classification Name:	Intravascular Catheter
	Product Code/ Regulation:	FOZ/21 CFR §880.5200
Predicate Device	Predicate Trade Name:	PowerGlide® Midline Catheter
	Classification Name:	Intravascular Catheter
	Premarket Notification:	K121073
	Manufacturer:	Bard Access Systems, Inc.
Device Description	Bard Access Systems, Inc.'s PowerGlide® 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 catheter rated for power injection. The PowerGlide® Midline Catheter is available in 18 and 22 gauge sizes. The 18 gauge size is available in 8cm or 10cm lengths and the 22 gauge size is available in only an 8cm length.	

Intended Use	The PowerGlide® 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® 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.
Technological Characteristics	Technological characteristics of the subject PowerGlide® Midline Catheter are substantially equivalent with respect to basic design 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 questions regarding safety or effectiveness.

Safety & Performance Tests

Verification and validation activities were designed and performed in accordance with Design Controls as per 21 CFR §820.30. The following guidance documents and standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device:

- *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, March 16, 1995*
- *BS EN ISO 10555-1: 2009, Sterile, single-use intravascular catheters, Part 1: General requirements*
- *ISO 10555-5: 1996, Sterile, single-use intravascular catheters, Part 5: Over-needle peripheral catheters*
- *ISO 11070: 1998, Sterile, single use intravascular catheter introducer*
- *Coronary and Cerebrovascular Guidewire Guidance, January 1995*
- *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*
- *ISO 9626: 2001, Stainless steel needle tubing for the manufacturer of medical devices*
- *ISO 23908: 2011, Sharps injury protection*
- *ISO 7864: 1993, Sterile hypodermic needles for single use*
- *ISO 23907: 2012, Sharps injury protection - Requirements and test methods - Sharps containers - First Edition*
- FDA Guidance: *Medical Devices with Sharps Injury Prevention Features, August 9, 2005*
- *AAMI/ANSI/ISO 10993-1:2009, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, and the FDA Modified ISO 10993 Test Profile*
- *#G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*
- *AAMI/ANSI/ISO 10993-7:2008, Biological Evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals*
- *AAMI/ANSI/ISO 11135:2007, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*
- *ASTM F640 (reapproved 2000), Standard Test Methods for Radiopacity of Plastics for Medical Use*
- *Design Control Guidance for Medical Device Manufacturers, March 11, 1997*

The subject device met all predetermined acceptance criteria derived from the above listed references and demonstrated substantially equivalent performance as compared to the cited predicate device.

Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject PowerGlide® Midline Catheter meets the requirements that are considered sufficient for its intended use and demonstrates that the subject device is substantially equivalent to the predicate device cited.

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

January 16, 2014

Bard Access Systems, Incorporated
Ms. Casey Coombs
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, UT 84116

Re: K133856
Trade/Device Name: PowerGlide® Midline Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: December 17, 2013
Received: December 19, 2013

Dear Ms. 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,

for

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

Enclosure

BARD
ACCESS SYSTEMS

Indications for Use

510(k) Number (if known): K133856

Device Name: PowerGlide® Midline Catheter

Indications for Use:

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.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR §801 Subpart D) (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner -S
Mary S. Runner -S DHHS
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