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

December 10, 2015

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

Re: K153298
Trade/Device Name: Accucath™ Intravascular Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: November 12, 2015
Received: November 13, 2015

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 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 yours,

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

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)*
K153298

Device Name
AccuCath Intravascular Catheter

Indications for Use *(Describe)*
The AccuCath Intravascular Catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids intravenously. This device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of therapy. The AccuCath IV Catheter is suitable for use with low pressure power injectors having a maximum pressure setting of 300 psi and maximum flow rate of 6mL/second.

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

510(k) Summary
21 CFR 807.92(a)

General Provisions	Submitter Name:	Bard Access Systems, Inc.
	Submitter Address:	605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Mr. Casey Coombs Regulatory Affairs Specialist
	Telephone Number:	(801) 522-5869
	Fax Number:	(801) 522-5425
	Date of Preparation:	9 December 2015
Subject Device	Trade Name:	AccuCath™ Intravascular Catheter
	Common Name:	Intravascular Catheter
	Classification Name:	Intravascular Catheter
	Product Code/ Regulation:	FOZ/21 CFR §880.5200
Predicate Devices	Predicate Trade Name:	AccuCath™ BC Intravascular Catheter System
	Classification Name:	Intravascular Catheter
	Premarket Notification:	K140504
	Manufacturer:	Bard Access Systems, Inc.
Device Description	The AccuCath™ Intravascular Catheter has usable length catheters of 1.25 and 2.25 inches in 18, 20, and 22 gauge sizes. The devices are single use, sterile intravascular catheters designed to be inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids intravenously. The AccuCath™ IV Catheter's hub has a built in blood control septum. The blood control feature is a single-use septum that automatically activates to stop the blood flow in the catheter hub when the needle is removed from the catheter during initial insertion by the clinician. Blood flow from the catheter hub will be restricted immediately after the needle retraction until a secure luer connection is made. The flow path is permanently opened once a secure luer connection has been made. The AccuCath™ IV Catheter is provided with a safety mechanism which allows the needle to be shielded following placement of the catheter. All devices have the basic structure of a protective cover, a catheter with a luer lock fitting, a needle connected to a flashback chamber, a safety container, and a guidewire within the lumen of the needle which is connected to a slider, spring and release button.	
Intended Use	The AccuCath™ Intravascular Catheter is intended to be inserted in the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously.	

Indications For Use

The AccuCath™ Intravascular Catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids intravenously. This device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of therapy. The AccuCath™ IV Catheter is suitable for use with low pressure power injectors having a maximum pressure setting of 300 psi and maximum flow rate of 6mL/second.

Technological Characteristics

Technological characteristics of the subject AccuCath™ Intravascular Catheter are substantially equivalent with respect to basic design and function to those of the cited predicate device.

Key modifications made to the subject device when compared to the predicate device are as follows:

- Dimensional modifications to introduce a 1.25 inch AccuCath™ Intravascular Catheter
- Modifications to the guidewire and seal components
- Dimensional modifications to the needle
- Modifications made to the guidewire, needle, and catheter interfaces
- Labeling and packaging modifications made due to subject 1.25 inch device, commercial name change, and packaging kit configurations
- Qualified additional sterilization locations

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

Subject and Predicate Device Comparison Table

Attribute	Subject Device – AccuCath™ Intravascular Catheter	Predicate Device – AccuCath™ BC Intravascular Catheter System (K140504)
Owner	Same	Bard Access Systems, Inc.
Classification	Same	FOZ - 21 CFR 880.5200 - Short-term - Intravascular Catheter
510(k) Status	Subject of this Premarket Notification	K140504 - Concurrence date July 17, 2014
Indications for Use	Same as predicate with the exception of the commercial name: The AccuCath™ Intravascular Catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids intravenously. This device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of therapy. The AccuCath™ IV Catheter is suitable for use with low pressure power injectors having a maximum pressure setting of 300 psi and maximum flow rate of 6mL/second.	The AccuCath™ BC Intravascular Catheter System is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids intravenously. This device may be used with consideration given to adequacy of vascular anatomy, appropriateness of the solution being infused, and duration of therapy. The AccuCath™ BC is suitable for use with low pressure power injectors having a maximum pressure setting of 300 psi and maximum flow rate of 6mL/ second.

Technological Characteristics

Subject and Predicate Device Comparison Table		
Attribute	**Subject Device – AccuCath™ Intravascular Catheter**	**Predicate Device – AccuCath™ BC Intravascular Catheter System (K140504)**
Commercial Name	AccuCath™ Intravascular Catheter	AccuCath™ BC Intravascular Catheter System
Catheter Dimensions	Length: 1.25 and 2.25 inches Diameter: 18, 20, 22 gauge	Length: 2.25 inches Diameter: 18, 20, 22 gauge
Duration of Use	Same	Short term (<30 days)
Primary Device Components	Same	Needle Guidewire Catheter
Means of Insertion	Same	Percutaneous, over a Guidewire
Insertion Site	Same	Peripheral
Primary Device Materials	Same	*Catheter Base Materials* • Shaft Tubing: Pebax® • Luer Connector: Polyurethane *Needle* • Stainless Steel *Guidewire* • Nitinol
Catheter Proximal Configuration	Same	Luer Connection
Catheter Distal Configuration	Same	Open Ended
Number of Lumens	Same	Single Lumen
Power Injection Maximum Flow Rate	Same	6 mL/s
Sterility	Same	Provided Sterile
Packaging Configurations	Standalone Configuration Basic Configuration Intermediate Configuration	Standalone Configuration

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

Test	Acceptance Criteria
Effective Length of Catheter	Test and report catheter length
Safety Activation	After deployment of the needle safety feature, the needle tip shall be sub-flush with the distal end of the housing
Gravity Flow	Test and report gravity flow rate with a 1000mm head pressure of water
Bleedback	No egress of blood over a period of 15 seconds
Guidewire Deployment/Retraction	Guidewire to deploy and retract smoothly per predetermined force requirements
Catheter Flashback	Flash is visible inside the catheter within a predetermined amount of time

Performance Tests

The following guidance documents and standards in conjunction with in-house protocols were used to determine the appropriate methods for evaluating the performance of the device:

- ISO 10993-1:2009, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 10555-1:2013, Sterile, Single-Use Intravascular Catheters – Part 1: General Requirements
- ISO 10555-5:2013, Intravascular Catheters – Sterile and Single-Use Catheters – Part 5: Over-Needle Peripheral Catheters
- ISO 7864:1993, Sterile Hypodermic Needles for Single Use
- ISO 9626:1991, Stainless Steel Needle Tubing for the Manufacture of Medical Devices
- ISO 594-1:1986, Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Equipment – Part 1: General Requirements
- ISO 594-2:1998, Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Equipment – Part 2: Lock Fittings
- ASTM F640:2012, Standard Test Methods for Determining Radiopacity for Medical Use
- ISO 11607-1:2006, Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems
- ISO 11607-2:2006, Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes
- ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals

Performance Tests	• ISO 11135:2014, Sterilization of Health-Care Products, Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices • FDA Guidance: Medical Devices with Sharps Injury Prevention Features, August 9, 2005 • Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, March 16, 1995 • 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 performance testing, the subject AccuCath™ Intravascular Catheter meets the requirements that are considered sufficient for its intended use and demonstrates that the subject device is substantially equivalent to the cited predicate device.