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

November 15, 2016

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

Re: K162894
Trade/Device Name: AccuCath™ Intravascular Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: October 13, 2016
Received: October 17, 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, 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)*

K162894

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 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

K162894

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:	Jacob Lee Regulatory Affairs Specialist
	Telephone Number:	(801) 522-5823
	Fax Number:	(801) 522-5425
	Date of Preparation:	October 13, 2016
Subject Device	Trade Name:	AccuCath™ Intravascular Catheter
	Common Name:	Intravascular Catheter
	Regulation Name:	Intravascular Catheter
	Product Code:	FOZ
	Regulation:	21 CFR §880.5200
	Regulatory Class:	Class II
	Classification Panel:	General Hospital
Predicate Devices	Predicate Trade Name:	AccuCath™ Intravascular Catheter
	Premarket Notification:	K153298 (cleared December 10, 2015)
	Manufacturer:	Bard Access Systems, Inc.
	Common Name:	Intravascular Catheter
	Regulation Name:	Intravascular Catheter
	Regulation:	21 CFR §880.5200
	Regulatory Class:	Class II
	Classification Panel:	General Hospital
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 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 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 power injectors.

Technological Characteristics

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

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

1. A change to remove and relocate the performance attributes associated with power injection (i.e. maximum pressure setting of 300 psi and flow rate of 6 mL /s) from the indications for use statement to a newly created power injection procedural section in the body of the instructions for use.
2. An update to the instructions for use to add a power injection procedural section to clarify the instructions related to power injection, as well as appropriate warnings and precautions related to power injection.

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™ Intravascular Catheter (K153298)
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	K153298 - Concurrence date December 10, 2015
Indications for Use	Proposed Indications for Use to remove the pressure setting and flow rate: 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 power injectors.	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.
Commercial	Same as predicate	AccuCath™ Intravascular

Technological Characteristics	**Name**		Catheter
	Catheter Dimensions	Same as predicate	Length: 1.25 & 2.25 inches Diameter: 18, 20, 22 gauge
	Duration of Use	Same as predicate	Short term (<30 days)
	Primary Device Components	Same as predicate	Needle Guidewire Catheter
	Means of Insertion	Same as predicate	Percutaneous, over a Guidewire
	Insertion Site	Same as predicate	Peripheral
	Primary Device Materials	Same as predicate	*Catheter Base Materials* • Shaft Tubing: Pebax® • Luer Connector: 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	6 mL/s
	Sterility	Same as predicate	Provided Sterile
	Packaging Configurations	Basic Configuration Intermediate Configuration	Standalone Configuration Basic Configuration Intermediate 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 subject device labeling modifications. The results of the risk analysis determined that no verification or validation activities were required because the subject device labeling modifications to the Indications for use and instructions for use 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 product instructions for use 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 AccuCath™ Intravascular Catheter is substantially equivalent to the cited predicate device.