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 5, 2016

C.R. Bard, Inc.
Bard Access Systems, Inc.
Silvia De La Barra
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, UT 84116

Re: K153190
Trade/Device Name: Zenysis™ Short-Term Dialysis Catheter
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: MPB
Dated: October 30, 2015
Received: November 3, 2015

Dear Silvia De La Barra,

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,

Joyce M. Whang -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*

K153190

Device Name

Zenysis™ Short-Term Dialysis Catheter

Indications for Use *(Describe)*

The Zenysis™ Short-Term Dialysis Catheter, is indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis, hemoperfusion, and apheresis treatments. The catheter is intended to be inserted in the jugular, femoral, or subclavian vein as required.

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.

BARD
ACCESS SYSTEMS

510(k) Summary
21 CFR 807.92(a)

General Provisions	Submitter Name: Address: Contact Person: Telephone Number: Fax Number: Date of Preparation:	Bard Access Systems, Inc. 605 North 5600 West Salt Lake City, UT 84116 Silvia De La Barra (801) 522-5909 (801) 522-5425 30 October 2015
Subject Device	Trade Name: Common Name: Classification Name: Product Code/ Regulation:	Zenysis™ Short-Term Dialysis Catheter Short-Term Dialysis Catheter Catheter, Hemodialysis, Non-Implanted MPB – 21 CFR §876.5540
Predicate Devices	Trade Name: Classification Name: Premarket Notification: Manufacturer:	Niagara™ Slim-Cath Short-Term Dialysis Catheters Short-Term Hemodialysis Catheter K010778 Bard Access Systems, Inc.
Reference Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	Power-Trialysis™ Slim-Cath™ Short-Term Dialysis Catheter Short-Term Hemodialysis Catheter K141531 Bard Access Systems, Inc.

Device Description

Zenysis™ Short-Term Dialysis Catheters are made of thermosensitive polyurethane, which softens when exposed to body temperature. The catheter is divided into two separate lumens permitting continuous blood flow. Both the venous (blue) and the arterial (red) lumens may be used for hemodialysis, hemoperfusion, and apheresis treatments.

The Attachable Suture Wing and Attachable Suture Wing Fastener will be used to support the Zenysis™ Short-Term Dialysis Catheter, as securement devices to fixate the exposed portion of the catheter shaft to the patient's skin.

The subject device included in this submission will be offered in varying French size and catheter configuration types, as summarized in the table below:

	Straight Extension Legs	Precurved Extension Legs
Insertion Length		12.5 cm
	15 cm	15 cm
	20 cm	20 cm
	24 cm	24 cm

The subject catheters will be packaged with legally marketed components used in the placement procedure.

Intended Use

Zenysis™ Short-Term Dialysis Catheters are recommended for use in attaining short term vascular access for hemodialysis, apheresis, and hemoperfusion treatments. This device is intended for insertion in the internal jugular, femoral, or subclavian vein as required.

Indications For Use

The Zenysis™ Short-Term Dialysis Catheter, is indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis, hemoperfusion, and apheresis treatments. The catheter is intended to be inserted in the jugular, femoral, or subclavian vein as required.

Technological Characteristics	Both the subject and predicate devices are intended for vascular access for hemodialysis, hemoperfusion, and apheresis treatments. The subject and predicate devices are based on the following same technological elements: • Short term use (<30 days) • Insertion technique-Seldinger (over-the-guidewire) or percutaneous procedure into one of the large central veins to place the catheter • Catheter is intended to be inserted in the jugular, femoral, or subclavian vein as required • Catheter tip placement is in the central venous system with the Superior Vena Cava (SVC) preferred • Catheter length 12.5 cm, 15 cm, 20 cm, and 24 cm • The tip configuration is an atraumatic tapered tip. The catheter is skived to create the venous and arterial lumen openings. • 11F DLPolyurethane catheter with one set of four round side holes per dialysis lumen located toward the distal end of the shaft. The following technological differences exist between the subject and predicate devices: • The subject device is a smaller French size, • The tip configuration of the subject device is an atraumatic tapered purple tip, where-as the predicate is staggered with a black tip, • Location of side holes are different between the subject and the predicate device, • The subject device has two more side holes than the predicate device, • The lumen geometry of the subject device is an ellipse-shaped, where as the predicate's lumens are round shaped. and • Different bifurcation design. The differences are not critical to the intended use of the device and do not raise any new questions regarding safety and/or effectiveness.

Safety & Performance Tests	Verification tests 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;* • *Draft Guidance for Industry and Food and Drug Administration Staff: Implanted Blood Access Devices for Hemodialysis, June 28, 2013;* • *ISO 10555-1:2013, Sterile, single-use intravascular catheters – Part 1: General requirements;* • *ISO 10555-3:2013, Sterile, single-use intravascular catheters – Part 3: Central Venous catheters;* • *ASTM F640:2012, Standard Test Methods for Determining Radiopacity for Medical Use;* • *ASTM F756:2013, Standard Practice for Assessment of Hemolytic Properties of Materials;* • *ASTM F1841:1997 (R2013), Standard Practice for Assessment of Hemolysis in Continuous Flow Blood Pumps; and* • *ISO 10993-1 CORR1:2010, Biological Evaluation of Medical Devices; Part 1 – Evaluation and Testing.* 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. Risk management, including a failure modes and effects analysis (FMEA), of the subject device was conducted in accordance with ISO 14971:2012, *Medical Devices – Risk Management for Medical Devices.* <u>Performance Testing – Bench:</u> • Priming Volumes • Assembly Leak Resistance • Hemolysis • Tip Tensile • Recirculation • Dialysis Flow Testing and Collapse • Shaft to Bifurcation Tensile • Radiopacity • Shaft Stiffness • Catheter Shaft Outer Dimensions • Extension Leg to Bifurcation Tensile • Assembly Burst Strength • Axial Restraint
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject Zenysis™ Short-Term Dialysis 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.