DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

April 17, 2017

C.R. Bard, Inc.
Christoph Wagner Von Hoff
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, Utah 84116

Re: K163001
Trade/Device Name: PowerFlow™ Implantable Apheresis IV Port
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port And Catheter
Regulatory Class: Class II
Product Code: PTD
Dated: March 13, 2017
Received: March 14, 2017

Dear Christoph Wagner Von Hoff:

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,

Michael J. Ryan -S

for 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)*
K163001

Device Name
PowerFlow™ Implantable Apheresis IV Port

Indications for Use *(Describe)*

The Bard PowerFlow™ Implantable Apheresis IV Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for long-term therapeutic apheresis, withdrawal of blood, and infusion of medications, I.V. fluids, parenteral nutrition solutions, blood and blood products.

The Bard PowerFlow™ Implantable Apheresis IV Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.

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)

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510(k) Summary: K163001

21 CFR 807.92

PowerFlow™ Implantable Apheresis IV Port with 9.6 Fr. ChronoFlex™ Catheter

1. General Provisions

Submitter Name:	Bard Access Systems, Inc.
Address:	605 North 5600 West Salt Lake City, UT 84116
Contact Person:	Christoph Wagner von Hoff
	Sr. Regulatory Affairs Program Manager
	Christoph.Wagnervonhoff@crbard.com
Phone:	480.638.2925
Fax:	480.449.2546
Date of Preparation:	14 April 2017

2. Subject Device

Trade Name:	PowerFlow™ Implantable Apheresis IV Port with 9.6 Fr. ChronoFlex™ Catheter
Common/Usual Name:	Subcutaneous implanted apheresis port
Classification Name:	Subcutaneous, implanted, intravascular infusion port and catheter
Regulatory Class:	II
Product Code:	PTD
Regulation:	21 CFR 880.5965

3. Predicate Device

Trade Name:	Bard CathLink 20 Titanium Port with Attachable Polyurethane Catheter
Classification Name:	Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Premarket Notification:	K926139
Manufacturer:	Bard Access Systems, Inc.

This predicate has not been subject to a design-related recall.

4. Reference Devices

Trade Name:	TriFusion, Model 0609190/0659350 (Hickman TriFusion Catheter)
Classification Name:	Percutaneous, Implanted, Long-term Intravascular Catheter
Premarket Notification:	K041088
Manufacturer:	Bard Access Systems, Inc.

Trade Name:	Titanium PowerPort ISP Implanted Port
Classification Name:	Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Premarket Notification:	K072215
Manufacturer:	Bard Access Systems, Inc.

5. Reference Devices Justification

Therapeutic Apheresis Reference Device

To support the use of the subject device for patients requiring therapeutic apheresis, The Hickman TriFusion Triple Lumen Long-Term Central Venous Catheter (TriFusion Catheter) cleared by the General Hospital Branch through K041088 is utilized as a reference predicate device. The TriFusion Catheter is a long-term intravascular catheter that is currently indicated for apheresis use. The means of inserting the catheter as well as the catheter tip location during clinical use are the same as what is utilized for the subject Bard PowerFlow Apheresis IV Port.

Power Injection Reference Device

The subject device will also have within the indications for use the power injection of contrast media when used with a power injection rated peripheral IV catheter. To substantiate the subject device for this use, the same test methods and acceptance criteria utilized for the Bard Titanium PowerPort ISP Implanted Port cleared through K072215 was used. The Bard Titanium PowerPort ISP Implanted Port has the same anatomical location when implanted as well as the same infusion capabilities as the subject device.

6. Device Description

The PowerFlow Implantable Apheresis IV Port with 9.6 Fr. ChronoFlex Catheter is designed to provide repeated access to the vascular system without the need for repeated venipuncture or the daily care of an external catheter. The Bard PowerFlow Apheresis IV Port is a low profile totally implantable, angled access titanium port based design and is accessed through an angled opening which consists of a funnel shaped entrance designed to guide the peripheral intravenous (P.I.V.) access needle and catheter into the subject device. The PowerFlow Apheresis IV Port comes with a number of kit components to aid in the implantation procedure and/or access of the device once implanted. The PowerFlow Apheresis IV Port and necessary kit components are provided sterile (EtO).

The overall implanted system consists of three primary components: the port body with a silicone layered septum, an attachable radiopaque polyurethane catheter, and a catheter lock which secures the catheter to the port body stem. The catheters used with infusion ports are essentially the same design as externalized, stand-alone intravascular catheters. Once implanted, the method of accessing the subject Bard PowerFlow Apheresis IV Port is the exact same as the predicate Bard CathLink 20 Titanium Port device. After the implanted device has been identified and access is prepped per institutional policy, the user palpates the uniquely shaped angled entry funnel. Once the funnel is palpated, providing the location of the introducer needle access path, the 14 or 16Ga introducer needle is inserted into the funnel. After the Introducer Needle Stop is reached, the Introducer Needle is pulled

back slightly and the P.I.V. Catheter is advanced forward. The P.I.V. Catheter is then advanced through the silicone layered septum and the Introducer Needle is removed. After needle removal, the Peripheral IV Catheter is attached to the appropriate extension set and secured for the necessary infusion or withdrawal procedure.

The PowerFlow Implantable Apheresis IV Port can be used for routine vascular access infusion or withdrawal using a BD Insyte Autoguard Shielded IV Catheter. For power injection infusion procedures, the subject device can be accessed with a power injection rated IV catheter to create a power-injectable system.

The kit components provided to aid in the implantation procedure and/or access of the device once implanted include:

Intermediate Implantation Placement Kit

- 16 Gauge Insyte Autoguard Shielded IV Catheter
- 17 Ga Flushing Connector
- Syringe, 12 cc with Luer Slip
- 9.5 Fr. Barbed Malleable Tunneler
- Introducer Needle, Echogenic 18 Gauge x 7cm
- StruXure Guidewire “J” Tip with Straightener, 0.035 inch OD x 70 cm length
- AirGuard Valved Introducer, Peel-Apart Sheath, 10 Fr. with Vessel Dilator

IV Port Access Kit

- 14 or 16 Gauge Insyte Autoguard Shielded IV Catheter
- Prep Pad, Skin
- Absorbent Towel
- ChloraPrep, 3mL
- GuardIVa
- Sentrinex 3D Port Dressing
- Extension Set, Macro, 9 inch Hex Luer Lock w/ Valve
- Face Mask
- Alcohol Wipe
- Pre-Filled Saline Syringe
- 2” x 2” Gauze
- Medical Adhesive Tape

7. Intended Use

PowerFlow Implantable Apheresis IV Ports are intended to be implanted vascular access devices designed to provide long-term, repeated access to the vascular system.

8. Indications for Use

The Bard PowerFlow™ Implantable Apheresis IV Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for long-term therapeutic apheresis, withdrawal of blood, and infusion of medications, IV fluids, parenteral nutrition solutions, blood and blood products.

The Bard PowerFlow™ Implantable Apheresis IV Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.

9. Technological Characteristics with Comparison to Predicate Device

The technological characteristics of the subject PowerFlow Implantable Apheresis IV Port with 9.6 Fr. ChronoFlex Catheter is substantially equivalent with respect to design and function to those of the predicate Bard CathLink 20 Titanium Port device. The subject device is designed to be accessed with a 14 or 16Ga BD Insyte Autoguard Shielded IV catheter and has a 9.6 Fr. ChronoFlex Catheter intended to provide optimal flow rates for patients requiring therapeutic apheresis.

An Implantable Port System with a valved silicone layered septum that is accessed with a peripheral IV catheter is the primary technological principle for both the subject and predicate device. Both port systems have the same three primary components which include a port body with a valved silicone layered septum, an attachable radiopaque polyurethane catheter, and a catheter lock which secures the catheter to the port body stem.

Different Technological Elements:

Feature	Subject Device (PowerFlow Apheresis IV Port)	Primary Predicate (CathLink 20 Titanium Port)	Impact on Safety	Impact on Effectiveness for Apheresis
Port Catheter Size	9.6 Fr polyurethane	6 Fr polyurethane	None – same outer diameter as existing port catheters	Same and/or higher flow rates possible to facilitate apheresis
IV Size	16 or 14 Gauge	20 Gauge	None – 16 Gauge needles are used for apheresis today; 14 Gauge needles are used to access fistulas today	Same and/or higher flow rates possible to facilitate apheresis
Silicone Valve	Single layer valve	Two layer valve	None – result is still a valve for use with an IV access	Single layer valve to facilitate multiple accesses
Entry Funnel	2.82 in^2 target area	2.46 in^2 target area	None – same size as intermediate size port septum	Larger and thus easier to find and identify
Port Body Materials	Titanium covered with silicone	Titanium	None – titanium and silicone are both biocompatible materials	Softer for patient comfort, provides multiple options for suture sites

Same Technological Elements:

Feature	Subject Device (PowerFlow Apheresis IV Port)	Primary Predicate (CathLink 20 Titanium Port)	Impact on Safety	Impact on Effectiveness for Apheresis
Long-term Duration of Use	repeated access	repeated access	Same for the predicate device and the subject device	Same for the predicate device and the subject device
Implanted Subcutaneously	tunneled and inserted into the blood vessel	tunneled and inserted into the blood vessel	Same for the predicate device and the subject device	Same for the predicate device and the subject device
Catheter Insertion Site	external jugular, internal jugular, or subclavian veins	external jugular, internal jugular, or subclavian veins	Same for the predicate device and the subject device	Same for the predicate device and the subject device
Catheter Tip Placement Location	lower 1/3 of the superior vena cava	lower 1/3 of the superior vena cava	Same for the predicate device and the subject device	Same for the predicate device and the subject device
Catheter Tip	Opened ended intravascular catheter tip design	Opened ended intravascular catheter tip design	Same for the predicate device and the subject device	Same for the predicate device and the subject device
Port System	Peripheral IV catheter accessed implantable port system	Peripheral IV catheter accessed implantable port system	Same for the predicate device and the subject device	Same for the predicate device and the subject device
Septum	Silicone valve and seal combination for layered septum	Silicone valve and seal combination for layered septum	Same for the predicate device and the subject device	Same for the predicate device and the subject device
Port Entry	Angled entry funnel with an introducer needle stop feature for port system access	Angled entry funnel with an introducer needle stop feature for port system access	Same for the predicate device and the subject device	Same for the predicate device and the subject device

10. 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:

- FDA Guidance on 510(k) Submissions for Implanted Infusion Ports, October 1990
- FDA Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, March 16, 1995
- FDA Guidance Medical Devices with Sharps Injury Prevention Features, August 9, 2005
- FDA Guidance Implanted Blood Access Devices for Hemodialysis, January 21, 2016
- FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016
- FDA Guidance Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Device Labeled as Sterile, 21 January 2016
- FDA Guidance Establishing safety and compatibility of passive implants in the magnetic resonance environment, August 21, 2008
- FDA Draft Guidance Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
- ISO 10555-1:2009, Sterile, single-use intravascular catheters, Part 1. General requirements
- ISO 10555-6: 2015, Intravascular catheters – Sterile and single use catheters Part 6: Subcutaneous implanted ports
- AAMI/ANSI/ISO 10993-1:2009, Biological Evaluation of Medical Devices Part 1: Evaluations and Testing, and the FDA Modified ISO 10993 Test Profile
- 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
- BS EN ISO 11135-1:2007, Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- BS EN 556-1: 2001, Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: Requirements for terminally sterilized medical devices
- AAMI ST72:2011, Bacterial endotoxins-Test methodologies, routine monitoring, and alternatives to batch testing (LAL)
- USP<85>:2012, Bacterial Endotoxins Test
- USP<161>:2009, Transfusion and Infusion Assemblies and Similar Medical Devices (define LAL limits for devices)
- ISTA 1G:2001, Packaged Products 150lb (68kg) or less Random Vibration
- ASTM D4332:2013, Standard practice for conditioning containers, packages, or packing components for testing
- ASTM F1980:2011, Standard guide for accelerated aging of sterile barrier systems for medical devices
- BS EN ISO 11607-1:2010, Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ASTM F136:2012, Standard specification for wrought titanium- aluminum-4 vanadium ELI alloy for surgical implant applications
- ASTM F86: 2013, Standard practice for surface preparation and marking of metallic surgical implants
- ASTM F640: 2012, Standard test methods for determining radiopacity for medical use
- ASTM F756:2008, Standard practice for assessment of haemolytic properties of materials

- ASTM F1841:2013, Standard practice for Assessment of Hemolysis in Continuous Flow Blood Pumps
- IEC 62366:2007, Medical devices – Application of usability engineering to medical devices – Edition 1.0
- ISO 15223-1:2012, Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
- KDOQI 2006: Clinical Practice Guidelines and Recommendations

Based upon the evaluation of the methods provided in the guidance and standards, the following verification tests were conducted:

- Port Subassembly Inspection
- Port Subassembly MR Compatibility
- Port Subassembly Radiopacity
- Stem-Catheter Connection Air Leak
- Peripheral IV Insertion Force
- Peripheral IV Retention Force
- Stem-Catheter Connection Tensile Strength
- Stem-Catheter Connection Hydraulic Burst
- Catheter Inspection
- Catheter Radiopacity
- Catheter Dimensions
- Catheter Vacuum Collapse
- Catheter Tensile Strength / Catheter Elongation
- Catheter Hydraulic Burst
- Tunneler-Catheter Connection Tensile
- Gravity Flow Rate
- Clearance Kinetics
- Apheresis Flow Rate
- Multiple Power Injection
- Device System Burst, Power Injection
- Recirculation
- Hemolysis
- Packaging Ship Testing
- Silicone Boot Retention
- Suture Retention
- Stem Tensile Strength
- Corrosion Resistance
- Peripheral IV Catheter Duration

The subject device met all pre-determined acceptance criteria and demonstrated substantial equivalence as compared to the predicate device.

11. Biocompatibility Testing

The subject device has different materials than the predicate device; however, all materials present in the subject device are used with the same patient contact in other Bard implantable vascular access ports. The biocompatibility evaluation was completed in compliance to ISO 10993-1:2009, Biological Evaluation of Medical Devices Part 1 – Evaluation and Testing within a Risk Management Process and the FDA Guidance for Industry and FDA- Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", as applicable to the device type. All biological tests were conducted by Bard or by independent testing contract laboratories in accordance with Good Laboratory Practice (GLP) standards.

The ISO 10993-1:2009 standard defines the Bard PowerFlow Implantable Apheresis IV Port as: Implant device, circulating blood, with permanent contact duration (>30 days)

The subject device does not contain any colorants. Final, finished, sterile samples of the subject Bard PowerFlow Implantable Apheresis IV Port assembly were used for all recommended biocompatibility tests. The tests listed below were conducted and evaluated per ISO 10993-1 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, and the FDA Modified ISO 10993 Test Profile.

- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity
- Acute systemic toxicity
- Subchronic systemic toxicity
- Genotoxicity
- Hemocompatibility
- Pyrogenicity
- Subcutaneous implantation (2, 8, 26 week) with histopathology
- Extractables and leachates

12. Testing Conclusion

The results of the testing performed successfully demonstrate that the subject device's performance is substantially equivalent to the predicate device and the scientific methods utilized from the reference devices are appropriate.

13. Clinical Data

Clinical data with the predicate device, CATHLINK 20, used in the therapeutic apheresis population have been reported in three studies[1,2,3.] Significant design similarities between the predicate CATHLINK 20 and the subject PowerFlow™ Implantable Apheresis IV Port suggest that this clinical data can provide reasonable expectations for the safety and effectiveness of the PowerFlow™ device.

In one study[1], 18 CATHLINK 20 ports were implanted in 15 patients with sickle cell disease for 19,230 catheter patient days. No peri-operative complications were observed. Three episodes of catheter occlusion required port replacement in two patients. One patient required port replacement after 23 months of continuous use; a second patient had their port replaced after continuous use for 16 months and then again 21 months after the first replacement. The observed rate for thrombotic occlusion was 0.16 per 1,000 catheter patient days. In the other 13 out of 15 patients, the median length of continuous port use was 45 months (range 30-64 months). Patients received erythrocytapheresis therapy on a monthly basis through their ports. The authors state that their experience indicates the CATHLINK 20 represents an effective, reliable, and safe means of establishing and maintaining venous access for patients requiring long-term erythrocytapheresis.

In a second study[2] of six patients, three started with a single device (using an antecubital or other peripheral vein for the second access point) and three started with two CATHLINK 20 devices. By the end of the study, 5 of 6 patients had two devices. Apheresis personnel were able to access the ports in 1.23 ± 0.6 attempts per port per procedure. Six of the 70 planned apheresis procedures were aborted. Of these, three were due to failure of the antecubital vein return site and three were because of catheter occlusion, which was resolved using a thrombotic agent. The other 64 therapeutic plasma exchange procedures were performed successfully. Two adverse surgical events occurred during the study: one was an infected skin suture site that required the replacement of another CATHLINK 20 at a different location and the other was a malpositioned catheter that required a return to the operating room for repositioning. No patient required hospitalization during the study. The authors state that the CATHLINK 20 provides adequate whole blood and plasma flow rates, is easy for apheresis personnel to access and manage, and does not burden the patient with lifestyle restrictions or exit site care.

The third study[3] followed four patients for approximately 1.5-2.5 years. Three of the patients had two devices and one patient had one CATHLINK 20 and used an antecubital vein for the second access point. For the 190 therapeutic plasma exchange procedures performed, the CATHLINK 20 device was accessed in 1.45 ± 0.86 attempts per device. Ninety-one percent (91%) of plasma exchange procedures were completed in <150 min (mean 120 ± 28min). There were no adverse effects resulting from the use of the CATHLINK 20 and no hospitalizations were needed for plasma exchange. The authors state that their follow-up experience indicates that the CATHLINK 20 could be conveniently used for long-term outpatient plasma exchange.

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[1] Raj A, Bertolone S, Bond S, et al. Cathlink® 20: A Subcutaneous Implanted Central Venous Access Device Used in Children With Sickle Cell Disease on Long-Term Erythrocytapheresis – A Report of Low Complication Rates. Pediatr Blood Cancer 2005 Jun 15; 44(7): 669-72.

[2] Pertine B, Razvi S, Weinstein R. Prospective investigation of a subcutaneous, implantable central venous access device for therapeutic plasma exchange in adults with neurological disorders. J Clin Apher 2002; 17:1-6.

[3] Gonzalez A, Sodano D, Flanagan J et al. Long-term therapeutic plasma exchange in the outpatient setting using an implantable central venous access device. J Clin Apher 2004; 19:180-184.

14. Summary of Substantial Equivalence

Based on the indications for use, technological characteristics, performance testing and biocompatibility testing the subject PowerFlow Implantable Apheresis IV Port with 9.6 Fr. ChronoFlex 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.