



Food and Drug Administration
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August 18, 2016

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

Re: K153440

Trade/Device Name: PowerLoc Max[®] Power-Injectable Infusion Set, SafeStep[®] Huber
Needle Set

Regulation Number: 21 CFR 880.5440

Regulation Name: Intravascular Administration Set

Regulatory Class: Class II

Product Code: FPA

Dated: July 19, 2016

Received: July 20, 2016

Dear Darlene Hull:

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,

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)

K153440

Device Name

PowerLoc MAX® Power-Injectable Infusion Set

Indications for Use

The PowerLoc MAX® Power-Injectable Infusion Set is an intravascular administration set with a non-coring right angle needle and manually activated needle stick prevention safety mechanism which reduces the risk of accidental needlestick injuries by shielding the needle. The needle is used to access surgically implanted vascular ports.

The PowerLoc MAX® Power-Injectable Infusion Set is indicated for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.

When used with ports that are indicated for power injection of contrast media into the central venous system, the PowerLoc MAX® Power-Injectable Infusion Set is also indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate at 11.8 cPs is 5 ml/s for 19 gauge and 20 gauge needles, and 2 ml/s for 22 gauge needles.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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FORM FDA 3881 (8/14)
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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*)

K153440

Device Name

SafeStep® Huber Needle Set

Indications for Use

The SafeStep® Huber Needle Set is a device intended for insertion into the septum of a subcutaneously implanted port and for the infusion of fluids into the port. The SafeStep® Huber Needle safety feature is manually activated during needle removal, and is designed to aid in the prevention of accidental needlesticks.

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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510(k) Summary K153440
21 CFR § 807.92(a)

<p align="center">General Provisions</p>	<p>Submitter Name: Bard Access Systems, Inc. Address: 605 North 5600 West Salt Lake City, UT 84116</p> <p>Contact Person: Darlene Hull Regulatory Affairs Specialist</p> <p>Telephone Number: (801) 522-5613 Fax Number: (801) 522-5425 Date of Preparation: 23 November 2015</p>
<p align="center">Subject Devices</p>	<p>Trade Name: PowerLoc MAX® Power-Injectable Infusion Set Common Name: Huber Needle Intravascular Administration Set Classification Name: Intravascular Administration Set Product Code/ Regulation: FPA 21 CFR § 880.5440</p> <p>Trade Name: SafeStep® Huber Needle Set Common Name: Huber Needle Intravascular Administration Set Classification Name: Intravascular Administration Set Product Code/ Regulation: FPA 21 CFR § 880.5440</p>
<p align="center">Predicate Devices</p>	<p>Trade Name: SafeStep® MAX Power-Injectable Infusion Set Classification Name: Intravascular Administration Set Premarket Notification:K073050 Manufacturer: Bard Access Systems, Inc.</p> <p>Trade Name: Luther Safety Huber Needle Set Classification Name: Intravascular Administration Set Premarket Notification:K040527 Manufacturer: Bard Access Systems, Inc.</p>

<p style="text-align: center;">Device Descriptions</p>	<p><u>PowerLoc MAX® Power-Injectable Infusion Set</u></p> <p>The PowerLoc MAX® Power-Injectable Infusion Set is a standard non-coring intravascular administration set with a non-coring Huber type right angle needle and a manually activated needle-stick prevention safety mechanism which reduces the risk of accidental needlestick injuries by shielding the needle. The device is used to access surgically implanted vascular ports and is indicated for use in the administration of fluids and drugs, as well as blood sampling.</p> <p>The PowerLoc MAX® Power-Injectable Infusion Set is also indicated for power injection of contrast media into the central venous system only through an implanted port that is also indicated for power injection. The maximum recommended infusion rate at 11.8 cPs is 5 ml/s for 19 gauge and 20 gauge needles and 2 ml/s for 22 gauge needles. The PowerLoc MAX® Power-Injectable Infusion Set is offered with and without a Y-site.</p> <p><u>SafeStep® Huber Needle Set</u></p> <p>The SafeStep® Huber Needle Set is a standard right angle Huber needle and administration set with a needlestick prevention feature, designed for use with a vascular access infusion system. It is manufactured with conventional medical grade, biocompatible materials. The SafeStep® Huber Needle Set operates as a standard Huber needle with the addition of a safety feature to aid in the prevention of needlestick injuries to the health practitioner. The SafeStep® Huber Needle Set is offered with and without a Y-site.</p> <p><u>Stabilization Device</u></p> <p>The stabilization device is intended for use as an accessory to the subject PowerLoc MAX® and SafeStep® infusion sets, and is supplied pre-loaded with the subject devices. It is placed centrally over the implanted port so that the base surrounds the implanted port under the skin. The infusion set needle handle is pressed down until the needle has entered the port septum, then the stabilization device is lifted off of the needle. The stabilization device is then discarded per hospital protocol.</p>
<p>Intended Use</p>	<p>Both the subject PowerLoc MAX® Power-Injectable Infusion Set and SafeStep® Huber Needle Sets, with and without the stabilization device, are intended for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.</p>
<p>Indications For Use</p>	<p><u>PowerLoc MAX® Power-Injectable Infusion Set</u></p> <p>The PowerLoc MAX® Power-Injectable Infusion Set is an intravascular administration set with a non-coring right angle needle and manually activated needle stick prevention safety mechanism which reduces the risk of accidental needlestick injuries by shielding the needle. The</p>

	<p>needle is used to access surgically implanted vascular ports.</p> <p>The PowerLoc MAX® Power-Injectable Infusion Set is indicated for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.</p> <p>When used with ports that are indicated for power injection of contrast media into the central venous system, the PowerLoc MAX® Power-Injectable Infusion Set is also indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate at 11.8 cPs is 5 ml/s for 19 gauge and 20 gauge needles, and 2 ml/s for 22 gauge needles.</p> <p><u>SafeStep® Huber Needle Set</u></p> <p>The SafeStep® Huber Needle Set is a device intended for insertion into the septum of a subcutaneously implanted port and for the infusion of fluids into the port. The SafeStep® Huber Needle safety feature is manually activated during needle removal, and is designed to aid in the prevention of accidental needlesticks.</p>
<p>Technological Characteristics</p>	<p>Technological characteristics including design and function of the subject devices, the PowerLoc MAX® Power-Injectable Infusion Set and SafeStep® Huber Needle Set without stabilization device, are similar with respect to those of the predicate devices, SafeStep® MAX Power-Injectable Infusion Set and Luther Safety Huber Needle Set.</p> <p>The subject devices may be used with a pre-loaded stabilization device accessory that is intended to stabilize the port during access and aid insertion of the needle into the port. The stabilization device utilizes materials that are a different formulation than materials used in the predicate devices, and have not been used in another legally marketed device within the same classification regulation with the same intended use. The stabilization device constitutes a change to the ergonomics of the patient/user interface of the subject devices, but does not change the design or function of the subject devices when used as an accessory to these devices.</p>
<p>Performance Tests</p>	<p>Verification and validation tests were performed in accordance with Design Controls per 21 CFR §820.30. The following performance data were referenced in support of the substantial equivalence determination. Testing was performed based on Bard Access Systems (BAS) internal test protocols as well as on existing standards that are relevant to the subject devices.</p> <p>Testing performed based on BAS internal test protocols are as follows:</p> <p>Slide Force testing was performed to ensure that the force required to slide the needle down the length of the stabilization device did not exceed the force required to insert the needle in</p>

the port septum.

Stabilization Device Removal Force testing was performed to ensure that it was not difficult to remove the stabilization device once the subject needle was inserted into the port.

Acceptability of the Stabilization Device to verify that the stabilization device was clinically acceptable in the placement of a port access needle.

Acceptability of GuardIva® with Stabilization Device to validate the use as directed in the IFU of the antimicrobial dressing with the stabilization device.

In addition to BAS internal protocols, the following guidance documents and standards were used to determine appropriate methods for evaluating the performance of the device:

- ISO 23908 First edition 2011-06-11 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- ISO 8536-4 Fifth edition 2010-10-01 Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed [Including: Amendment 1 (2013)]10.
- BS EN ISO 8536-10:2015 Infusion equipment for medical use - Part 10: Accessories for fluid lines for single use with pressure infusion equipment.
- ISO 10993-1 Fourth edition, 2009-10-15 – Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process.
- ISO 10993-7: 2008 – Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.
- ISO 11135: 1994 – Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization.
- BS EN ISO 11607-1 Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems.
- ISO 594-1: 1986, Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Equipment.
- ISO 594-2: 1998, Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 2: Lock Fittings.
- ISO 9626 AMD 1: 2001 – Stainless Steel Needle Tubing for Manufacture of Medical Devices.
- ISO 10555-1: 2013 – Intravascular catheters – Sterile and

	<p>single-use catheters – Part 1: General requirements.</p> <ul style="list-style-type: none"> • ISO 11137-1: 2006 – Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. • ISO 7864: 1993 – Sterile hypodermic needles for single use. • FDA Guidance Medical Devices with Sharps Injury Prevention Features issued August 9, 2005. • FDA Guidance Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment issued December 11, 2014. <p>The subject devices met all predetermined acceptance criteria derived from the above listed references and demonstrated substantially equivalent performance as compared to the cited predicate devices.</p> <p>Risk management, including a failure modes and effects analysis (FMEA), of the subject device was conducted in accordance with BS EN ISO 14971:2012, <i>Medical Devices – Risk Management for Medical Devices</i>.</p>
<p>Summary of Substantial Equivalence</p>	<p>Based on the intended use, technological characteristics, and safety and performance testing, the subject PowerLoc MAX® Power-Injectable Infusion Set and SafeStep® Huber Needle Set used with and without the stabilization device meet the requirements that are considered sufficient for its intended use as compared to the predicate devices cited. Therefore, the subject devices are substantially equivalent to the predicates.</p>