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

August 8, 2017

C.R. Bard, Inc.
Jeremy Tidwell
Quality/Regulatory Specialist
605 North 5600 West
Salt Lake City, Utah 84116

Re: K171735
Trade/Device Name: PowerLoc® MAX Power-Injectable Infusion Set and SafeStep® Huber Needle Set
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle.
Regulatory Class: Class II
Product Code: PTI
Dated: July 11, 2017
Received: July 13, 2017

Dear Jeremy Tidwell:

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,

James P. Bertram -S

for

Lori A. Wiggins, MPT, CLT
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)*

K171735

Device Name
PowerLoc® MAX Power-Injectable Infusion Set

Indications for Use *(Describe)*

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.

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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*
K171735

Device Name
SafeStep® Huber Needle Set

Indications for Use *(Describe)*
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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BARD
ACCESS SYSTEMS

510(k) Summary

21 CFR 807.92(a)

General Provisions	Submitter Name: Bard Access Systems, Inc. Address: 605 North 5600 West Salt Lake City, UT 84116 Contact Person: Jeremy Tidwell Quality/Regulatory Affairs Specialist Telephone Number: 801-522-5665 Fax Number: 801-522-4969 Date of Preparation: August 4, 2017
Subject Devices	Subject Trade Name: PowerLoc® MAX Power-Injectable Infusion Set Common Name: Huber Needle Intravascular Infusion Set Kit Regulation Name: Non-Coring (Huber) Needle Product Code: PTI Regulation: 21 CFR §880.5570 Regulatory Class: II Classification Panel: General Hospital
	Subject Trade Name: SafeStep® Huber Needle Set Common Name: Huber Needle Intravascular Infusion Set Kit Regulation Name: Non-Coring (Huber) Needle Product Code: PTI Regulation: 21 CFR §880.5570 Regulatory Class: II Classification Panel: General Hospital
Predicate Devices	Predicate Trade Name: PowerLoc® MAX Power-Injectable Infusion Set Premarket Notification: K153440 Manufacturer: Bard Access Systems, Inc. Common Name: Huber Needle Intravascular Administration Set Regulation Name: Intravascular Administration Set Product Code: FPA Regulation: 21 CFR §880.5440 Regulatory Class: II Classification Panel: General Hospital
	Predicate Trade Name: SafeStep® Huber Needle Set Premarket Notification: K153440 Manufacturer: Bard Access Systems, Inc. Common Name: Huber Needle Intravascular Administration Set Regulation Name: Intravascular Administration Set Product Code: FPA Regulation: 21 CFR §880.5440 Regulatory Class: II Classification Panel: General Hospital

Purpose Statement	The purpose of this submission is to clear the subject devices (i.e., PowerLoc® MAX Power-Injectable Infusion Set and SafeStep® Huber Needle Set with or without the stabilization accessory) in new packaging configurations that include additional kit components, all of which are legally marketed devices.
Device Descriptions	**PowerLoc® MAX Power-Injectable Infusion Set** The PowerLoc® MAX Power-Injectable Infusion Set is a standard non-coring intravascular infusion 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 also includes an integrated extension set consisting of infusion tubing, a non-vented male Luer cap, female Luer lock adapter, pinch clamps, and safety guard handle and base. It 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. 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. **SafeStep® Huber Needle Set** The SafeStep® Huber Needle Set is a standard right angle Huber needle and infusion set with a needlestick prevention feature, designed for use with a vascular access infusion system. The device also includes an integrated extension set consisting of infusion tubing, a non-vented male Luer cap, female Luer lock adapter, pinch clamps, and safety guard handle and base. 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. **Stabilization accessory** The stabilization accessory is intended for use as an accessory to the subject PowerLoc® MAX Power-Injectable Infusion Set and SafeStep® Huber Needle Set, 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 accessory is lifted off of the needle. The stabilization accessory is then discarded per hospital protocol.
Intended Use	Both the subject PowerLoc® MAX Power-Injectable Infusion Set and SafeStep® Huber Needle Set with or without the stabilization accessory, are intended for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.
Indications For Use	**PowerLoc® MAX Power-Injectable Infusion Set** 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.

<table>
<tr><td>Indications For Use Cont.</td><td>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.

<u>SafeStep® Huber Needle Set</u>

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.</td></tr>
<tr><td>Technological Characteristics</td><td>Technological characteristics including design and function of the subject devices, the PowerLoc® MAX Power-Injectable Infusion Set and SafeStep® Huber Needle Set with or without the stabilization accessory are the same as those of the predicate devices, PowerLoc® MAX Power-Injectable Infusion Set and SafeStep® Huber Needle Set with or without the stabilization accessory.

The following table provides a comparison between the technological characteristics of the subject and predicate device:

<table>
<tr><th colspan="3">Comparison between subject PowerLoc® MAX Power-Injectable Infusion Set (with or without the stabilization accessory) and the predicate PowerLoc® MAX Power-Injectable Infusion Set (with or without the stabilization accessory)</th></tr>
<tr><th>Device Attribute</th><th>Subject:
PowerLoc® MAX Power-Injectable Infusion Set (with or without the stabilization accessory)</th><th>Predicate K153440:
PowerLoc® MAX Power-Injectable Infusion Set (with or without the stabilization accessory)</th></tr>
<tr><td>Owner</td><td>Bard Access Systems, Inc.</td><td>Bard Access Systems, Inc.</td></tr>
<tr><td>Product Code</td><td>PTI
21 CFR 880.5570
Non-Coring Huber Needle</td><td>FPA
21 CFR 880.5440
Set, Administration, Intravascular</td></tr>
<tr><td>Review Branch</td><td>Center For Devices and Radiological Health (CDRH)</td><td>Center For Devices and Radiological Health (CDRH)</td></tr>
<tr><td>510k Status</td><td>Subject of this Premarket Notification</td><td>K153440
Concurrence Date: August 18, 2016</td></tr>
<tr><td>Intended Use</td><td>Same as predicate.</td><td>The PowerLoc® MAX Power-Injectable Infusion Set is intended for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.</td></tr>
<tr><td>Indications for Use</td><td>Same as predicate.</td><td>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</td></tr>
</table>
</td></tr>
</table>

Technological Characteristics Cont.	**Indications for Use Cont.**		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.
	General Device Description	Same as predicate.	The PowerLoc® MAX Power-Injectable Infusion Set is a non-coring Huber needle infusion set with an integral needle stick prevention safety feature. The stabilization device is an accessory to the Huber needle infusion sets which is placed centrally over the implanted port to assist in the placement of the Huber needle in the implanted port.
	Y-Site	Same as predicate.	The PowerLoc® MAX Power-Injectable Infusion Set is offered either with or without a Y-site.
	Duration of Use	PowerLoc® MAX: Same as predicate. Stabilization accessory: Same as predicate.	PowerLoc® MAX: Externally communicating device with an indirect blood path with a contact duration of >24 hours to 30 days. Stabilization accessory: A single-use device used only for the duration of the insertion of the needle into the port. Surface device, skin only, limited exposure (≤24 hours).
	Device Materials	Same as predicate.	Huber Needle Stainless Steel
		Same as predicate.	Adhesive UV Adhesive
		Same as predicate.	Safety Guard Base Styrene, Butadine, Copolymer or Polycarbonate

Technological Characteristics Cont.	**Device Materials Cont.**	Same as predicate.	Needle Lubricant Medical Grade Silicones
		Same as predicate.	Safety Guard Inner Base Styrene, Butadine, Copolymer Insert Colorants: Yellow Brown Black
		Same as predicate.	Safety Guard Sleeve Stainless Steel
		Same as predicate.	Safety Guard Shutter Stainless Steel
		Same as predicate.	Pad-print Ink Ink
		Same as predicate.	Needle Cover Polyetheylene
		Same as predicate.	Safety Guard Handle Styrene, Butadine, Copolymer
		Same as predicate.	Comfort Pad Polyethylene
		Same as predicate.	Administration Tubing PVC
		Same as predicate.	Female Locking Luer Connection PVC
		Same as predicate.	Adaptable Y-Injection Site Female Locking Luer Connection PVC
		Same as predicate.	Non-vented Male Luer Cap Acrylonitrile butadiene styrene
		Same as predicate.	Pinch Clamps Polypropylene Colorants Yellow Brown Black
		Same as predicate.	Stabilization accessory Stabilizer Polycarbonate

Technological Characteristics Cont.		Same as predicate.	<u>Stabilization accessory</u> Needle Handle Polypropylene		
	Sterility Method	Same as predicate.	Ethylene Oxide		
	Sterility Assurance Level (SAL)	Same as predicate.	SAL 10^{-6}		
	Number of Uses	Same as predicate.	Single-use device		
	Anatomical Site Use	Same as predicate.	The site of a surgically implanted vascular port.		
	Principle of Operation	Same as predicate.	The device accesses implanted ports in order to transport fluid into, and out of, the central venous system. It utilizes a standard right angle non-coring Huber type needle and infusion set with an integral safety engineered needlestick prevention feature in order to do this.		
	Safety Infusion Set Device Components	Same as predicate.	End Cap Luer connector Tubing Non-Winged Grip Safety Guard Base Marked Pinch Clamps Needle Needle handle Stabilization accessory		
	Sizes	Same as predicate.	Needle Gauge - 19, 20 or 22 Needle Length - 0.75 in., 1.00 in., 1.50 in.		
	Needle OD	Same as predicate.	Needle Gauge	Needle OD mm (in.)	Clamp Color
			19G	1.054 – 1.080 (0.0415 – 0.0425)	Brown
			20G	0.889 – 0.914 (0.0350 – 0.0360)	Yellow
			22G	0.699 – 0.724 (0.0275 – 0.0285)	Black
	Tubing Dimension Summary for device without Y-Injection Site	Same as predicate.	Needle Gauge	Inner Diameter / Outer Diameter	Length
			19G	0.048 in. / 0.088 in.	8 in.
			20G	0.041 in. / 0.088 in.	8 in.
			22G	0.034 in. / 0.088 in.	8 in.
	Tubing	Same as predicate.	Needle	Inner / Outer	Length

Technological Characteristics Cont.

Dimension Summary for device with Y-Injection Site		Gauge	Diameter	Diameter	
		19G	0.048 in.	0.088 in.	4 in.
		20G	0.041 in.	0.088 in.	4 in.
		22G	0.034 in.	0.088 in.	4 in.
Packaging	Header Pouch – Uncoated 1073B Tyvek® nylon, LDPE HDPE	Pouch – 1059B Tyvek® and TPF, PET Based Adhesive Lamination			
Kit Components –(only configurations offered are with or without the stabilization accessory)	Mask (2) Hand Sanitizer (2) Gloves (Silver) Absorbent Towel Fenestrated Drape Chloraprep, 3 mL Gloves, Purple Nitrile GuardIVa® Antimicrobial Hemostatic Dressing Skin Protectant Pad Pre-Filled Saline Syringe Sentrinex™ 3D Port Dressing	None			

Comparison between subject SafeStep® Huber Needle Set (with or without the stabilization accessory) and the predicate SafeStep® Huber Needle Set (with or without the stabilization accessory)		
Device Attribute	**Subject: SafeStep® Huber Needle Set with or without the stabilization accessory**	**Predicate K153440: SafeStep® Huber Needle Set with or without the stabilization accessory**
Owner	Same as predicate.	Bard Access Systems, Inc.
Product Code	PTI 21 CFR 880.5570 Non-Coring Huber Needle	FPA 21 CFR 880.5440 Set, Administration, Intravascular
Review Branch	Same as predicate.	Center For Devices and Radiological Health (CDRH)
510k Status	Subject of this Premarket Notification	K153440 Concurrence Date: August 18, 2016
Intended Use	Same as predicate.	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.

Technological Characteristics Cont.	**Indications for Use**	Same as predicate.	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.
	General Device Description	Same as predicate.	The SafeStep® Huber Needle Set is a non-coring Huber needle infusion set with an integral needle stick prevention safety feature. The stabilization device is an accessory to the Huber needle infusion sets which is placed centrally over the implanted port to assist in the placement of the Huber needle in the implanted port.
	Y-Site	Same as predicate.	The SafeStep® Huber Needle Set is offered either with or without a Y-site.
	Duration of Use	SafeStep®: Same as predicate. Stabilization accessory: Same as predicate.	SafeStep®: Externally communicating device with an indirect blood path with a contact duration of >24 hours to 30 days. Stabilization accessory: A single-use device used only for the duration of the insertion of the needle into the port. Surface device, skin only, limited exposure (≤24 hours).
	Device Materials	Same as predicate.	Huber Needle Stainless Steel
		Same as predicate.	Adhesive UV Adhesive
		Same as predicate.	Safety Guard Base Styrene, Butadine, Copolymer or Polycarbonate
		Same as predicate.	Needle Lubricant Medical Grade Silicones – Dow 360 or MED-4149 or MED-361
		Same as predicate.	Safety Guard Inner Base Styrene, Butadine, Copolymer Insert Colorants: Yellow Brown Black

Technological Characteristics Cont.	**Device Materials Cont.**	Same as predicate.	Safety Guard Sleeve Stainless Steel
		Same as predicate.	Safety Guard Shutter Stainless Steel
		Same as predicate.	Needle Cover Polyetheylene
		Same as predicate.	Safety Guard Handle Styrene, Butadine, Copolymer
		Same as predicate.	Comfort Pad Polyethylene
		Same as predicate.	Administration Tubing PVC
		Same as predicate.	Female Locking Luer Connection PVC
		Same as predicate.	Needleless Access Connector Y-Site Polycarbonate Silicone
		Same as predicate.	Non-vented Male Luer Cap Acrylonitrile butadiene styrene
		Same as predicate.	Pinch Clamps Polypropylene Colorants Yellow Brown Black
		Same as predicate.	Stabilization accessory Stabilizer Polycarbonate
		Same as predicate.	Stabilization accessory Needle Handle Polypropylene
	Sterility Method	Same as predicate	Ethylene Oxide
	Sterility Assurance Level (SAL)	Same as predicate	SAL 10^{-6}
	Number of Uses	Same as predicate	Single-use device
	Anatomical Site Use	Same as predicate	The site of a surgically implanted vascular port.

Technological Characteristics Cont.

Principle of Operation	Same as predicate	The device accesses implanted ports in order to transport fluid into, and out of, the central venous system. It utilizes a standard right angle non-coring Huber type needle and infusion set with an integral safety engineered needlestick prevention feature in order to do this.
Safety Infusion Set Device Components	Same as predicate	End Cap Luer connector Tubing Non-Winged Grip Safety Guard Base Pinch Clamps Needle Needle handle Stabilization accessory
Sizes	Needle Gauge - Same as predicate. Needle Length - Same as predicate.	Needle Gauge - 19, 20 or 22 Needle Length - 0.75 in., 1.00 in., 1.50 in.

Needle Outside Diameter

Same as predicate.

Needle Gauge	Needle OD mm (in.)	Clamp Color
19G	1.054 – 1.080 (0.0415-0.0425)	Brown
20G	0.889-0.914 (0.0350-0.0360)	Yellow
22G	0.699-0.724 (0.0275-0.0285)	Black

Tubing Dimension Summary for device without Y-injection Site

Same as predicate

Needle Gauge	Inner Diameter	Outer Diameter	Length
19G	0.048 in.	0.088 in.	8 in.
20G	0.041 in.	0.088 in.	8 in.
22G	0.034 in.	0.088 in.	8 in.

Tubing Dimension Summary for device with Y-injection Site

Same as predicate

Needle Gauge	Inner Diameter	Outer Diameter	Length
19G	0.048 in.	0.088 in.	4 in.
20G	0.041 in.	0.088 in.	4 in.
22G	0.034 in.	0.088 in.	4 in.

Packaging	Header Pouch – Uncoated 1073B Tyvek®, nylon, LDPE, HDPE	Pouch – 1059B Tyvek® and TPF, PET Based Adhesive Lamination

Technological Characteristics Cont.

Kit Components- (only configurations offered are with or without the stabilization accessory)	Mask (2) Hand Sanitizer (2) Gloves (Silver) Absorbent Towel Fenestrated Drape Chloraprep, 3 mL Gloves, Purple Nitrile GuardIVa® Antimicrobial Hemostatic Dressing Skin Protectant Pad Pre-Filled Saline Syringe Sentrinex™ 3D Port Dressing	None

Safety & Performance Tests

The following table identifies the regulatory information for each component used in the subject device kits.

Kit Component (Trade Name /Manufacturer Name)	Regulation Number	Classification	Regulatory Coverage
Mask	21 CFR 878.4040	Class II	K110455
Hand Sanitizer Packet	N/A	OTC Drug	NDC21749-530-01
STERLING* Nitrile Gloves	21 CFR 880.6250	Class I	K081089
Absorbent Towel	21 CFR 878.4370	Class II	K862801
Fenestrated Drape	21 CFR 878.4370	Class II	K111458
ChloraPrep™ Solution One-Step Applicator, 3 mL	N/A	OTC Drug	NDA020832
PURPLE NITRILE* Gloves	21 CFR 880.6250	Class I	K051347
GuardIVa® Antimicrobial Hemostatic IV Dressing	Unclassified	Unclassified	K121485
Prep Pad, Skin Protectant	21 CFR 880.5090	Class I Exempt	N/A
Sentrinex™ 3D Port Dressing	21 CFR 878.4020	Class I Exempt	N/A
Syringe, Sodium Chloride (Saline) 0.9%, 10 mL[a]	21 CFR 880.5200	Class II	K120836

[a]Component is included in kits as a post-sterile operation; it is sterilized separately, prior to kitting.

Testing was performed to show that the kit components maintain their biological safety and functional efficacy after ethylene oxide (EO) sterilization. The kit components met all predetermined acceptance criteria. Risk management, including a failure modes and effects analysis (FMEA), of the subject devices was conducted in accordance with BS EN ISO 14971:2012, *Medical Devices – Risk Management for Medical Devices*. The risks were analyzed, mitigated and reduced to an acceptable level, and re-evaluation showed that the remaining risks are outweighed by the benefits of the device, and that the device is acceptable for its intended use.

Summary of Substantial Equivalence	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 with or without the stabilization accessory included in kit configurations, 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.