November 27, 2024

Bard Access Systems, Inc.
Catherine Langford
Regulatory Affairs Specialist
605 North 5600 West
Salt Lake City, Utah 84116

Re: K241353
Trade/Device Name: PowerLoc™ Max Power Injectable Infusion Set; SafeStep™ Huber Needle Set
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: PTI
Dated: October 28, 2024
Received: October 28, 2024

Dear Catherine Langford:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Porsche Bennett
for David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241353

Device Name
PowerLoc™ Max Power Injectable Infusion Set; SafeStep™ Huber Needle Set

Indications for Use *(Describe)*

PowerLoc™ Max Power Injectable Infusion Set:
The PowerLoc™ Max Power Injectable Infusion Set is a device intended for insertion into the septum of a subcutaneously implanted port for the infusion 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. These devices may be used in any patient population with an implanted vascular port.

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.

SafeStep™ Huber Needle Set:
The SafeStep™ Huber Needle Set is a device intended for insertion into the septum of a subcutaneously implanted port for the infusion of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.

These devices may be used in any patient population with an implanted vascular port.

Note: The SafeStep™ Huber Needle Set is NOT indicated for power injection of contrast media or any other high pressure injection.

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, Inc.
605 N 5600 West
Salt Lake City, Utah 84116

K241353 - 510(k) Summary
21 CFR 807.92(a)

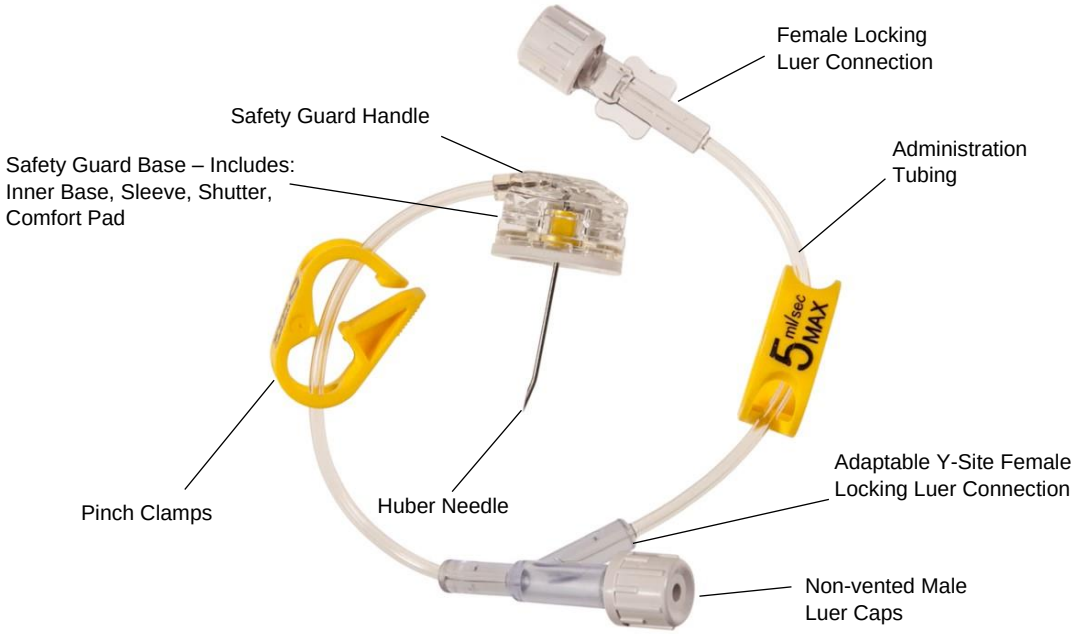
Contact Details 21 CFR 807.92(a)(1)	Submitter Name:	Bard Access Systems, Inc.
	Submitter Address:	605 North 5600 West Salt Lake City, Utah 84116 USA
	Contact Telephone:	801.522.5000
	Contact Person:	Catherine Langford Regulatory Affairs Specialist
	Contact Email	catherine.langford@bd.com
	Date of Preparation:	27 November 2024
Device Name 21 CFR 807.92(a)(2)	Trade Name:	PowerLoc™ Max Power Injectable Infusion Set; SafeStep™ Huber Needle Set
	Common Name:	Hypodermic single lumen needle
	Classification Name:	Non-Coring (Huber) Needle
	Class:	Class II
	Regulation Number:	880.5570
	Product Code:	PTI
	Classification Panel:	General Hospital
Predicate Device 21 CFR 807.92(a)(3)	Trade Name:	PowerLoc® MAX Power-Injectable Infusion Set; SafeStep® Huber Needle Set
	Common Name	Hypodermic single lumen needle
	Classification Name:	Non-Coring (Huber) Needle
	Class:	Class II
	Regulation Number:	880.5570
	Product Code:	PTI
	Premarket Notification Number:	K171735

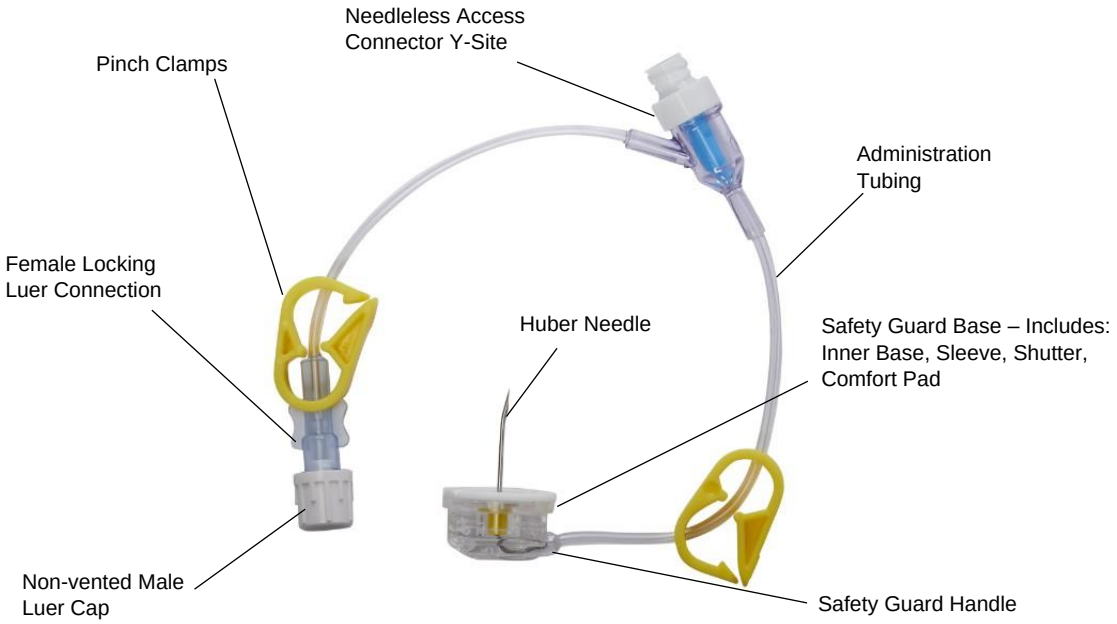
Indications for Use 21 CFR 807.92(a)(5)

PowerLoc™ Max Power Injectable Infusion Set:
The PowerLoc™ Max Power Injectable Infusion Set is a device intended for insertion into the septum of a subcutaneously implanted port for the infusion 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. These devices may be used in any patient population with an implanted vascular port.

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.

SafeStep™ Huber Needle Set:
The SafeStep™ Huber Needle Set is a device intended for insertion into the septum of a subcutaneously implanted port for the infusion of fluids and drugs, as well as blood sampling through surgically implanted vascular ports.

	These devices may be used in any patient population with an implanted vascular port. Note: The SafeStep™ Huber Needle Set is NOT indicated for power injection of contrast media or any other high pressure injection.
Device Description 21 CFR 807.92(a)(4)	**PowerLoc™ Max Power Injectable Infusion Set** PowerLoc™ Max Power Injectable Infusion set is a non-coring Huber needle and infusion set with a manually activated needlestick prevention safety mechanism. These devices access surgically implanted subcutaneous vascular ports by penetrating the port septum to provide a closed fluid pathway for the infusion of fluids and drugs, as well as blood sampling. In addition, it may be used for power injection of contrast media through an implanted vascular port that is also indicated for power injection up to 325 psi (2241 kPa). It is supplied sterile and non-pyrogenic, for single use only. 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 device intended for insertion into the septum of a subcutaneously implanted port for the infusion of fluids and drugs, as well as blood sampling through surgically implanted vascular ports. These devices may be used in any patient population with an implanted vascular port. **Note:** The SafeStep™ Huber Needle Set is **NOT** indicated for power injection of contrast media or any other high pressure injection.
Diagrams	 **Subject PowerLoc™ Max Power Injectable Infusion Set (19 GA with Y-site shown)**



Subject SafeStep™ Huber Needle Set (19 GA with needleless Y-site shown)

Indications for Use Comparison 21 CFR 807.92(a)(5)	The subject device, PowerLoc™ Max Power Injectable Infusion Set and SafeStep™ Huber Needle Set, intended use have not changed compared to the predicate; however, the wording has been modified to be clearer and more succinct. The intended use remains the same with no expansion or change in the purpose of the device or how it functions.

	Component	SUBJECT DEVICE PowerLoc™ Max Power Injectable Infusion Set SafeStep™ Huber Needle Set	PREDICATE DEVICE (K171735) PowerLoc™ Max Power Injectable Infusion Set SafeStep™ Huber Needle Set
Technological Comparison 21 CFR 807.92(a)(6)	Huber Needle	Same as predicate	Stainless Steel
	Adhesive	Same as predicate	UV Cured Acrylic
	Needle Lubricant	Silicone	Silicone
	Needle Cover	Same as predicate	Polyethylene
	Safety Guard Base	Same as predicate	Styrene-Butadiene Copolymer or Polycarbonate
	Safety Guard Inner Based	Same as predicate	Styrene-Butadiene Copolymer + Colorant 19GA (Yellow) 20GA (Brown) 22GA (Black)
	Safety Guard Sleeve	Same as predicate	Stainless steel
	Safety Guard Shutter	Same as predicate	Stainless steel
	Safety Guard Handle	Same as predicate	Styrene-Butadiene Copolymer
	Safety Guard Comfort Pad	Same as predicate	Polyethylene
	Administration Tubing	**Thermoplastic polyurethane**	Polyvinyl chloride
	Female Locking Luer Connection	**Polyvinyl chloride (Type of PVC and dimension)**	Polyvinyl chloride
	Adaptable Y-Injection site Female Locking Luer Connection	Same as predicate	Polyvinyl chloride
	Non-vented Male Luer Cap	Same as predicate	Acrylonitrile butadiene styrene + White Colorant
	Pinch Clamp	**Acetal (polyoxymethylene) + Colorant** **19G: Brown** **20G: Yellow** **22G: Black**	Polypropylene + Colorant 19G: Brown 20G: Yellow 22G: Black
	Pinch Clamp Ink (PowerLoc™ Max Power Injectable Infusion Set ONLY)	White Ink Black Ink	White Ink Black Ink
	Needless Access Connector Y-Site	Same as predicate	Polycarbonate

(SafeStep™ Huber Needle Set ONLY)		
Needless Access Connector Y-Site Valve (SafeStep™ Huber Needle Set ONLY)	Same as predicate	Silicone
Fundamental Scientific Technology	Same as predicate	The device accesses implanted ports to transport fluid into and out of the central venous system. It utilizes a standard right angle non-coring Huber needle and administration set with a needlestick prevention feature.
Device Sizes and Tubing Dimensions	Same as predicate	Needle Gauge – 19G, 20G or 22G Needle Length – 0.75 in., 1.00 in., 1.50 in. Clamp Color Guided by ISO 6009 – 19G Brown, 20G Yellow, 22G Black Tubing dimension **with** needleless Y-site – 4.00 in Tubing dimension ***without*** needleless Y-site – 8.00 in
Product Configurations	Same as predicate	Standalone and convenience kit
Sterilization Modality	Ethylene Oxide	Ethylene Oxide
Minimum SAL	Same as predicate	1×10^{-6}
Anatomical Site Use	Same as predicate	The site of a surgically implanted vascular port.
Disposable or Reusable	Same as predicate	Disposable – Single-use device
Safety Infusion Set Device Components	End Cap Luer Connector Tubing Non-Winged Grip Safety Guard Base Pinch Clamps Needle Needle Handle	End Cap Luer Connector Tubing Non-Winged Grip Safety Guard Base Pinch Clamps Needle Needle Handle

	Subject Device **PowerLoc™ Max Power Injectable Infusion Set**	**Predicate Device (K171735)** **PowerLoc™ Max Power Injectable Infusion Set**
Gauge (G)	Power Injector Flow Rate at 11.8 cPs at 325 psi (2241 kPa)	Power Injector Flow Rate at 11.8 cPs at 325 psi (2241 kPa)
19	Same as predicate	5 mL/s
20	Same as predicate	5 mL/s
22	Same as predicate	2 mL/s

	Subject Device **PowerLoc™ Max Power Injectable Infusion Set** **SafeStep™ Huber Needle Set**	**Predicate Device (K171735)** **PowerLoc™ Max Power Injectable Infusion Set** **SafeStep™ Huber Needle Set**	
		Device Description	**Attribute**
Priming Volume *(on labeling)*	Same as predicate	Without Y-site	0.3 mL
		SafeStep™ with needleless Y-site	0.7 mL
		PowerLoc™ Max with Y-site	0.4 mL
Residual Volume	Same as predicate	SafeStep™ with needleless Y-site	<.35 mL
Connector Types	Same as predicate	Without Y-site	1 Female Luer lock adapter
		SafeStep™ with needleless Y-site	1 Female Luer lock adapter 1 Needleless Y-site connector
		PowerLoc™ Max with Y-site	1 Female Luer lock 1 Y-site Luer lock connector

Comment 1: The material formulation for the administration tubing and pinch clamps have changed to those currently used in a similarly marketed device (K060812) with the same biological contact and duration. Biocompatibility and performance testing were conducted to demonstrate the differences do not raise new or different questions of safety and effectiveness.

Comment 2: The type of PVC material was changed for the female Luer locking connection and there were dimensional changes to the female Luer locking connection to comply with ISO80369-7. Biocompatibility and performance testing; respectively were conducted to demonstrate the differences do not raise new or different questions of safety and effectiveness.

In summary, the subject and predicate devices utilize the same fundamental scientific technologies. The subject device is substantially equivalent to the predicate device with respect to components, component materials, and dimensions. In addition, the BD-owned subject and predicate devices were designed in compliance with the same consensus standards.

Safety & Performance Tests
21 CFR 807.92(b)

The following performance tests were conducted by or for Bard Access Systems (BD) per guidance documents and standards in conjunction with in-house protocols to establish the performance of the PowerLoc™ Max Power Injectable Infusion Set and SafeStep™ Huber Needle Set, and in determining substantial equivalence to the predicate K171735. All testing passed the predetermined acceptance criteria.

Reference Standard: *ISO 10993-1:2009 – Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process*	
Biocompatibility Testing	Tests to confirm that the catheter is free from biological hazard per testing. A health-based risk assessment per ISO 10993-1 was performed for determining the acceptability of the material for the intended purpose. Testing Performed includes: • Cytotoxicity • Sensitization • Irritation or Intracutaneous Reactivity • Acute Systemic Toxicity • Pyrogenicity • Subchronic Systemic Toxicity • Hemocompatibility
Reference Standard: *ISO 10555-1:2013 – Sterile Single-Use Intravascular Catheters – Part 1: General requirements*	
Assembly Burst	Burst pressure test to confirm the assembly burst pressure exceeds the peak pressure at maximum flow conditions.
Reference Standard: *ISO 8536-4:2019 – Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed*	
Assembly Tensile	Test to demonstrate the peak tensile force of each assembly exceeds the minimum peak tensile force.
Reference Standard: *ISO 8536-10:2015 – Infusion equipment for medical use – Part 10: Accessories for fluid lines for single use with pressure infusion equipment*	
Assembly Air Leak	Test to confirm that the assembly will not leak when occluded.
Assembly High Pressure Water Leak/Burst (2X)	Test to confirm the PowerLoc™ Max Power Injectable Infusion Set does not leak or burst at maximum indicated flow rate.
Reference Standard: *ISO 7864:2016: Sterile hypodermic needles for single use – Requirements and test methods*	
Assembly Occlusion/Flow Rate	Test to confirm minimum flow rates.

	Internal Standard	
	Clamp Function	Test to confirm that fluids will not pass through tubing when the clamp is engaged.
	Reference Standard: ***ISO 80369-7: Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications***	
	Luer Adapter Testing	Testing to ensure that Luer adapters meet requirements for: • Leak • Leak Decay • Stress Cracking • Resistance to Separation from Axial Load • Resistance to Separation from Unscrewing • Resistance to Overriding
	Reference Standard: ***USP<788>: Sizing and Counting Particulate Matter***	
	Particulate Testing	Testing to ensure that particulate matter on the catheter post-manufacture is not exceeded for prescribed particle sizes.
	Reference Standard: ***Guidance for Industry and FDA Staff: Intravascular Administration Sets Premarket Notification Submissions [510(k)] (Document Issued July 11, 2008)***	
	Needleless Y-Site Testing	Testing to ensure needleless access connector used in SafeStep™ Huber Needle Set configurations with Y-site meet requirements for: • Microbial Ingress • Valve Activation • Air Introduction Due to Device Connect/Disconnect
	Reference Standard: ***ISO 10993-7:2008: Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]***	
	Residual Toxicity	Testing to ensure EO residuals are below requirements for any patient with an implanted port.
	Clinical Testing	Clinical data was not needed to demonstrate substantial equivalence.
Technological Comparison to Predicate Device	The subject PowerLoc™ Max Power Injectable Infusion Set and SafeStep™ Huber Needle Set has the same intended use and fundamental technological characteristics as the cited predicate device cleared under K171735. The tubing and clamp materials differ from the predicate device; however, this difference does not alter the intended use of the subject device and does not raise any new or different questions regarding safety or effectiveness when compared to the predicate device.	
Summary of Substantial Equivalence	Based on the intended use, technological characteristics, and results of performance testing, the subject PowerLoc™ Max Power Injectable Infusion Set and SafeStep™ Huber Needle Set is considered substantially equivalent to the cited predicate device.	