



December 14, 2017

Infusion Safety Products, Inc.
% Audrey Swearingen
Director, Regulatory Affairs
Emergo Global Consulting, LLC
2500 Bee Cave Rd., Bldg. 1, Suite 300
Austin, Texas 78746

Re: K170881

Trade/Device Name: ISP Safety Huber Needle Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: November 17, 2017
Received: November 21, 2017

Dear Audrey Swearingen:

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,

 Tina
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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

Indications for Use

510(k) Number (if known)

K170881

Device Name

ISP Safety Huber Needle Infusion Set

Indications for Use (Describe)

The ISP Safety Huber Needle Infusion Set is a safety IV administration set with a non-coring, ninety degree, right angled Huber needle, used to access a patient's surgically implanted vascular port. The ISP Safety Huber Needle Infusion Set is intended to administer fluids or to withdraw blood through the implanted vascular port. The ISP Safety Huber Needle Infusion Set facilitates safe removal of the needle by encapsulating the needle within the wing to help prevent needlestick injuries when using the device for vascular port access.

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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ISP Safety Huber Needle Infusion Set

K170881

1. Submission Sponsor

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2. Submission Correspondent

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Contact: Audrey Swearingen, RAC

Title: Director, Regulatory Affairs

3. Date Prepared

December 7, 2017

4. Device Identification

Trade/Proprietary Name: ISP Safety Huber Needle Infusion Set

Common/Usual Name: Huber Needle Administration Set

Classification Name: Hypodermic Single Lumen Needle

Regulation Number: 880.5570

Product Code: PTI

Device Class: Class II

Classification Panel: General Hospital Devices

5. Legally Marketed Predicate Device(s)

K993848 - Millennium Huber Plus Safety Infusion Set, Millennium Medical Distribution, Inc.

6. Indication for Use Statement

The ISP Safety Huber Needle Infusion Set is a safety IV administration set with a non-coring, ninety degree, right angled Huber needle, used to access a patient's surgically implanted vascular port. The ISP Safety Huber Needle Infusion Set is intended to administer fluids or to withdraw blood through the implanted vascular port. The ISP Safety Huber Needle Infusion Set contains a sharps injury prevention feature that facilitates safe removal of the needle by encapsulating the needle within the wing to help prevent needlestick injuries when using the device for vascular port access.

7. Device Description

The Infusion Safety Products, Inc. ISP Safety Huber Needle Infusion Set is a non-coring safety IV administration set used to access a patient's surgically implanted vascular port. The Safety Huber Needle Infusion Set is constructed with a 90°, non-coring Huber needle that is available in 19ga, 20ga and 22ga and in ½", ¾", 1" and 1½" lengths. It is offered in the following model numbers:

19 ga needle	20 ga needle	22 ga needle
ISP195	ISP205	ISP225
ISP195Y	ISP205Y	ISP225Y
ISP1975	ISP2075	ISP2275
ISP1975Y	ISP2075Y	ISP2275Y
ISP191	ISP201	ISP221
ISP191Y	ISP201Y	ISP221Y
ISP1915	ISP2015	ISP2215
ISP1915Y	ISP2015Y	ISP2215Y

The device is lipid resistant and contains non-latex containing products. The PVC Tubing is non-DEHP, with a flow rate of approximately 5cc per sec. max / CT rated to 300 psi. The Safety Huber Needle Infusion Set is packaged in a semi-rigid form fill and seal package with a 1059B Tyvek® lid. The sets are sterilized using a validated ethylene oxide method.

The ISP Safety Huber Needle Infusion Set is intended to administer fluids or withdraw blood through the implanted vascular port (not included with the ISP Safety Huber Needle Infusion Set device). The device is offered in the following configurations, each with various needle gauges and needle lengths:

1. Huber needle in a needle holder in a safety wing, a 7.50" length of PVC Tubing, ratchet clamp, female luer lock and vented-protector cap. Approximate Priming Volume: 0.25cc.
2. Huber needle in a needle holder in a safety wing, a 4.12" length of PVC tubing with a ratchet clamp attached to a Y port with a non-vented cap, a second 4.12" length of PVC off the Y port with a

ratchet clamp, a female luer lock and non-vented protector cap. Approximate Priming Volume: 0.35cc.

The ISP Safety Huber Needle Infusion Set facilitates safe removal of the needles by encapsulating the needle within the wing to help prevent needle stick injuries when using the device for vascular port access. The safety mechanism is engaged when the needle is removed from the access port. As the set is removed from the patient, the wing encapsulates the needle, making an audible click when secure, to prevent needle sticks to the clinician.

8. Substantial Equivalence Discussion

The following table compares the ISP Safety Huber Needle Infusion Set to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities and differences to the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	Multi-Med, Inc. for Infusion Safety Products, Inc.	Millennium Medical Distribution, Inc.	Device Comparison
Trade Name	ISP Safety Huber Needle Infusion Set	Millennium Huber Plus Safety Needle Infusion Set (K993848)	
Product Code	PTI	FPA	Different.
Regulation Number	880.5570	880.5440	Different
Regulation Name	Hypodermic Single Lumen Needle	Intravascular administration set	Different; both are Huber needles with tubing for intravascular administration
Indications for Use	The ISP Safety Huber Needle Infusion Set is a safety IV administration set with a non-coring, ninety degree, right angled Huber needle, used to access a patient's surgically implanted vascular port. The ISP Safety Huber Needle Infusion Set is intended to administer fluids or to withdraw blood through the	The Millennium Huber Plus Safety Infusion Set is a safety IV administration set with a non-coring, ninety-degree, right-angle Huber needle, used to access surgically implanted vascular ports. The Huber needle is used to administer fluids or to withdraw blood. The Huber Plus system facilitates safe removal of	Same

Manufacturer	Multi-Med, Inc. for Infusion Safety Products, Inc.	Millennium Medical Distribution, Inc.	Device Comparison
Trade Name	ISP Safety Huber Needle Infusion Set	Millennium Huber Plus Safety Needle Infusion Set (K993848)	
	implanted vascular port. The ISP Safety Huber Needle Infusion Set contains a sharps injury prevention feature that facilitates safe removal of the needle by encapsulating the needle within the wing to help prevent needlestick injuries when using the device for vascular port access.	the needle by encapsulating the needle within the attachment wings to help prevent needlestick injuries when using the device for vascular port access.	
Mechanism of Action	Standard Huber needle infusion set operation. When the needle is removed from the patient a portion of the wing automatically surrounds the needle to prevent accidental needle-stick injuries.	Standard Huber needle infusion set operation. When the needle is removed from the patient a portion of the wing automatically surrounds the needle to prevent accidental needle-stick injuries.	Same
Needle Gauges	19, 20, 22	19, 20, 22	Same
Needle Lengths	½, ¾, 1, 1½ inches	½, ¾, 1, 1½ inches	Same
Materials	Medical grade 304 stainless steel, K-Resin SBC, Medical grade PVC, Medical grade polypropylene, Tubing: Medical grade non-DEHP PVC	Medical grade 304 stainless steel, Medical grade polypropylene, Cryolite G20, Medical grade PVC, Tubing: Medical grade non-DEHP PVC	Same for most components. Biocompatibility testing demonstrates equivalence in that no different questions of safety are raised.
Tubing Lengths	7.5" (without Y-port); 8.24" (with Y-port)	7" (without Y-port); 8.5" (with Y-port)	Same; minor variations do not raise new questions of safety or effectiveness
Sterile, Single-Use	Yes	Yes	Same

Manufacturer	Multi-Med, Inc. for Infusion Safety Products, Inc.	Millennium Medical Distribution, Inc.	Device Comparison
Trade Name	ISP Safety Huber Needle Infusion Set	Millennium Huber Plus Safety Needle Infusion Set (K993848)	
Performance:			Same or Similar; small variations do not raise different questions of safety or effectiveness
Force to lock safety wings	160 – 180g (Chatillon gauge)	240 – 260g (Chatillon gauge)	
Force to Insert Needle	2.20 – 2.75 lbs	2.20 – 2.65 lbs	
Force to Remove Needle	2.20 – 2.50 lbs	2.20 – 2.50 lbs	
Puncture resistance of wings	5.9 – 6.1 lbs	5.5 – 6.0 lbs	
Bond separation forces	All bonds withstood 10 lbs force	All bonds withstood 10 lbs force	
Occlusions at 45 psi	None	None	
Leaks at 100 psi	None	None	
Tested to ISO 23908	Yes, passed	Not known	N/A

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of ISP Safety Huber Needle Infusion Set and in showing substantial equivalence to the predicate device, Infusion Safety Products, Inc. completed a number of non-clinical performance tests. The ISP Safety Huber Needle Infusion Set passed all the testing in accordance with internal requirements, national standards, and international standards for overall design, sterilization, biocompatibility, and performance, with test results confirming that the design output meets the design inputs and specifications for the device.

Performance comparison tests supporting substantial equivalence to the predicate device are listed below:

- Needle Insertion/Removal Force – Comparison testing showed the same forces are required for both the subject and predicate device. Passed.
- Occlusion Testing – Neither the subject nor the predicate device showed occlusions at 45 psi. Passed.
- Leak Testing - Neither the subject nor the predicate device showed occlusions at 100 psi; the ISP Safety Huber Needle Infusion Set also had no leaks when tested at 330 psi. Passed.
- Bonding Forces – All devices tested withstood 10 lbs. of force. Passed.
- Flow Rate – Both devices achieved a rate of 45 ml/min at 150 mmHg. Passed.

- Simulated clinical study - Puncture resistance forces of the safety wings were the same for the subject and predicate devices; subject device required less force to lock the safety wings into place than the predicate; both subject and predicate safety wing were successfully activated 200 times without failure. Passed all tests.

Additional device testing included:

- Sharps injury protection testing (ISO 23908) – Activation force of the safety wing met acceptance criterion of ≤ 2.5 lbs; Force to remove needle from port and continue full activation met acceptance criterion of ≤ 5 lbs at each of three (3) pull speeds; Force to over-ride Safety Wing feature met the requirement to withstand minimum of 8 lbs force. Passed.
- Simulated Use testing - The ISP Safety Huber Needle Infusion Set was demonstrated as safe and effective in preventing potential needle-stick injuries, and that the device may be used with one hand. Passed.
- Biocompatibility – The subject device passed acceptance criteria for cytotoxicity (ISO 10993-5); irritation/intracutaneous reactivity, sensitization (ISO 10993-10); systemic toxicity and subchronic toxicity (ISO 10993-11); hemocompatibility (ISO 10993-4) including hemolysis, partial thromboplastin, complement activation assay (c3a), and complement activation assay (sc5b-9). Passed all tests.
- Sterilization by ethylene oxide (ISO 11135) and ethylene oxide residual testing (AAMI/ANSI/ISO 10993-7) – Obtained SAL of 10^{-6} ; EO residuals met the release acceptance criteria of <4 mg/daily dose of EO and <9 mg/daily dose of ECH. Passed.
- Bacterial endotoxin (ANSI/AAMI ST 72:2011) – devices contained <2.0 EU/device, meeting the requirement of 20 EU/device for blood contact devices. Passed.
- Shelf life testing (ASTM F1980-07, ASTM F1929-15, ISO 11737-1, ISO 11737-2) – sterility and seal integrity was maintained to support a 2 year expiration date. Passed.
- Transportation testing (ISTA 6-FedEx-A) – Packaging and devices withstood free fall drop, compression, and vibration. Passed.
- Conical Luer Fitting testing (ISO 594-1) - Connectors measured within the two limit planes of the gauge with no evidence of rocking the gauge and the fitting. Passed.
- Lipid Resistance - All devices passed the functional testing after 72 hours exposure; no evidence of cracking or crazing. Passed.
- Tensile strength – All devices withstood 10 lbs. of force. Passed.
- Core testing (ASTM F3212) – No coring was observed at 40x magnification. Passed.

10. Statement of Substantial Equivalence

Based on the data, the ISP Safety Huber Needle Infusion Set is determined to be substantially equivalent to the predicate device.