Jiangsu Caina Medical Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120 CN

Re: K200463
Trade/Device Name: Huber Needle Infusion Set, Safety Huber Needle Infusion Set
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: PTI
Dated: February 1, 2021
Received: March 8, 2021

Dear Diana Hong:

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. 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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

James M. Simpson Jr -S7

for Payal Patel
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200463

Device Name

Huber Needle Infusion Set
Safety Huber Needle Infusion Set

Indications for Use *(Describe)*

Huber Needle Infusion Set

The Huber Needle Infusion Set is a device with a non-coring right angle needle intended for insertion into the septum of a subcutaneously implanted port and for the infusion of fluids and drugs, as well as blood sampling into the port.

The 19G-22G needles of device are also suitable for power injection of contrast media to a maximum pressure of 325psi. When used with ports indicated for power injection, the maximum recommended infusion rate is approximately 5ml/s for 19G and 20G, 2ml/s for 22G.

Safety Huber Needle Infusion Set

The Safety Huber Needle Infusion Set is a device with a non-coring right angle needle intended for insertion into the septum of a subcutaneously implanted port and for the infusion of fluids and drugs, as well as blood sampling into the port. The safety feature is manually activated during needle removal, and is designed to aid in the prevention of accidental needle sticks.

The 19G-22G needles of device are also suitable for power injection of contrast media to a maximum pressure of 325psi. When used with ports indicated for power injection, the maximum recommended infusion rate is approximately 5ml/s for 19G and 20G, 2ml/s for 22G.

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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K200463

1. Date of Preparation: 3/31/2021

2. Sponsor Identification
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4. Identification of Proposed Device

Trade Name: Huber Needle Infusion Set, Safety Huber Needle Infusion Set
Common Name: Intravascular Administration Set
Regulatory Information
Classification Name: Hypodermic Single Lumen Needle
Classification: II
Product Code: PTI
Regulation Number: 21 CFR 880.5570
Review Panel: General Hospital;

5. Identification of Predicate Device
510(k) Number: K170897
Product Name: Surecan Safety II

Indication for Use:
Huber Needle Infusion Set
The Huber Needle Infusion Set is a device with a non-coring right angle needle intended for insertion into the septum of a subcutaneously implanted port and for the infusion of fluids and drugs, as well as blood sampling into the port.

The 19G-22G needles of device are also suitable for power injection of contrast media to a maximum pressure of 325psi. When used with ports indicated for power injection, the maximum recommended infusion rate is approximately 5ml/s for 19G and 20G, 2ml/s for 22G.

Safety Huber Needle Infusion Set
The Safety Huber Needle Infusion Set is a device with a non-coring right angle needle intended for insertion into the septum of a subcutaneously implanted port and for the infusion of fluids and drugs, as well as blood sampling into the port. The safety feature is manually activated during needle removal, and is designed to aid in the prevention of accidental needle sticks.

The 19G-22G needles of device are also suitable for power injection of contrast media to a maximum pressure of 325psi. When used with ports indicated for power injection, the maximum recommended infusion rate is approximately 5ml/s for 19G and 20G, 2ml/s for 22G.

Device Description:
The Huber Needle Infusion Set and Safety Huber Needle Infusion Set non-coring angled needle are single use, sterile and non-pyrogenic 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 the port. The Huber Needle Infusion Set and Safety Huber Needle Infusion Set are available in different gauge sizes (25G, 24G, 22G, 20G, 19G) and length (0.5", 0.75", 1.0", 1.24", 1.5"). The 19G-22G needles of device are suitable for power injection of contrast media into the central venous system only through an implanted port that is indicated for power injection at a maximum pressure of 325psi. For power injection of contrast media, the maximum recommended infusion rate is approximately 5ml/s for 19G and 20G and 2ml/s for 22G.The 24G and 25G needles of device should not be used with power injectors. The Huber Needle Infusion Set is available in five models (S-1, S-2, Y-1, Y-2, D-1), and the Safety Huber Needle

Infusion Set is available in four models (S-1s, S-2s, Y-1s, Y-2s).

The safety feature is manually activated during needle removal, and is designed to aid in the prevention of accidental needlestick. After activation, the non-coring needle is locked in the safety mechanism-plate. The device also have Y-sites with Y-needleless adapters or Y-needle adapters for secondary access. The needleless adapters eliminate the risk of needlestick.

6. Summary of Technological Characteristics

Table 1 Comparison of Technological Characteristics with the Predicate Device

Item	**Proposed Device Huber Needle Infusion Set**	**Proposed Device Safety Huber Needle Infusion Set**	**Predicate Device K170897**	**Remake**
Product Code	PTI	PTI	PTI	Same
Regulation No.	880.557	880.557	880.557	Same
Class	II	II	II	Same
Indication for Use	The Huber Needle Infusion Set is a device with a non-coring right angle needle intended for insertion into the septum of a subcutaneously implanted port and for the infusion of fluids and drugs, as well as blood sampling into the port. The 19G-22G needles of device are also suitable for power injection of contrast media to a maximum pressure of 325psi. When used with ports	The Safety Huber Needle Infusion Set is a device with a non-coring right angle needle intended for insertion into the septum of a subcutaneously implanted port and for the infusion of fluids and drugs, as well as blood sampling into the port. The safety feature is manually activated during needle removal, and is designed to aid in the prevention of accidental needle sticks. The 19G-22G needles of device are also suitable for power injection of contrast media to a maximum pressure of	The Surecan Safety II power-injectable safety non-coring needle 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 the port. The Surecan Safety II safety feature is manually activated during needle removal, and is designed to aid in the prevention of accidental needle-sticks. When used with ports that are	Similar 1

Item	Proposed Device Huber Needle Infusion Set	Proposed Device Safety Huber Needle Infusion Set	Predicate Device K170897	Remake
	indicated for power injection, the maximum recommended infusion rate is approximately 5ml/s for 19G and 20G, 2ml/s for 22G.	325psi. For power injection of contrast media, the maximum recommended infusion rate is approximately 5ml/s for 19G and 20G, 2ml/s for 22G.	indicated for power injection of contrast media into the central venous system, the Surecan Safety II needle is also indicated for power injection of contrast media. For power injection of contrast media, the maximum flow rates at 325 psi are 5mL/s for 19 gauge and 20 gauge needles and 2mL/s for the 22 gauge needles.	
Configuration	Non-coring needle	Non-coring needle	Non-coring needle	Similar 2
	NA	Safety mechanism-hub	Safety mechanism-hub	
	PVC tube	PVC tube	PVC tube	
	Clamps	Clamps	Clamps	
	Female luer fitting	Female luer fitting	Female luer fitting	
	Male luer cap	Male luer cap	Male luer cap	
	Needleless connector	Needleless connector	Needleless connector	
	Y needleless adapters	Y needleless adapters	Y needleless adapters	
	Y needle adapters	Y needle adapters	Y needle adapters	
	NA	Safety Mechanism	Safety Mechanism	
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Complied with 21 CFR part 801	
Needle gauge	19G, 20G, 22G, 24G, 25G	19G, 20G, 22G, 24G, 25G	19G, 20G, 22G	Different 3
Needle length	0.5 " , 0.75 " , 1 " , 1.25 " , 1.5 "	0.5 " , 0.75 " , 1 " , 1.25 " , 1.5 "	0.5 " , 0.6 " , 0.8 " , 1 " , 1.3 " , 1.5 "	Different 4

Item	Proposed Device Huber Needle Infusion Set	Proposed Device Safety Huber Needle Infusion Set	Predicate Device K170897	Remake
Available for use with contrast media	19G, 20G, 22G	19G, 20G, 22G	19G, 20G, 22G	Same
Infusion rate with contrast media	5ml/s for 19G and 20G 2ml/s for 22G	5ml/s for 19G and 20G 2ml/s for 22G	5ml/s for 19G and 20G 2ml/s for 22G	Same
Needle bevel design	Non-coring needle	Non-coring needle	Non-coring needle	Same
Priming volume	S-1: 0.4mL S-2: 0.5mL Y-1: 0.7mL Y-2: 0.7mL D-2: not applicable	S-1s: 0.4mL S-2s: 0.5mL Y-1s: 0.7mL Y-2s: 0.7mL	19ga (without Caresite)- 0.32mL 20ga (without Caresite)- 0.24mL 22ga (without Caresite)- 0.18mL 19ga (with Caresite)- 0.62mL 20ga (with Caresite)- 0.53mL 22ga (with Caresite)- 0.46mL	Different 5
Safety Mechanism				
Safety Mechanism Design	NA	The activation of the safety device is manual. After the infusion is completed, hold the base of the safety mechanism-plate with one hand, hold the double wing with the other hand and pull the needle out. When the needle is completely pulled out until the click sound is heard, the tip of the needle is locked in the safety mechanism-plate.	Manually activated safety mechanism upon removal of the needle from the implanted vascular port. Safety mechanism locks needle into place when a firm stop is felt. A green dot appears on the clear bottom plate when safety mechanism is fully engaged.	Different 6

Item	Proposed Device Huber Needle Infusion Set	Proposed Device Safety Huber Needle Infusion Set	Predicate Device K170897	Remake
Does the device have wings?	NA	Yes	Yes	Same
Is the engagement of the safety mechanism visible to the user?	NA	Yes	Yes	Same
Hub	Methyl methacrylate acrylonitrile butadiene styrene plastics (MABS)	NA	Unknown	Non-clinical testing performed. Does not raise new question of safety and effectiveness.
Joint pipe	Polyvinyl chloride (PVC)	NA		
PVC tube	Polyvinyl chloride (PVC)	Polyvinyl chloride (PVC)		
Female Luer fitting	Methyl methacrylate acrylonitrile butadiene styrene plastics (MABS); Polypropylene (PP) White Color	Methyl methacrylate acrylonitrile butadiene styrene plastics (MABS); White Color		
Needleless connector	Polycarbonate (PC)+Silicone rubber	Polycarbonate (PC) +Silicone rubber		
Y needleless adapters	Polycarbonate (PC) + Silicone rubber	Polycarbonate (PC) + Silicone rubber		
PVC extend tube	Polyvinyl chloride (PVC)	Polyvinyl chloride (PVC)		
Y needle adapters-connector	Methyl methacrylate acrylonitrile butadiene styrene plastics (MABS)	Methyl methacrylate acrylonitrile butadiene styrene plastics (MABS)		
Y needle adapters-injection site	Silicone rubber	Silicone rubber		
Lubricant	Polydimethylsiloxane	Polydimethylsiloxane		

Item	Proposed Device Huber Needle Infusion Set	Proposed Device Safety Huber Needle Infusion Set	Predicate Device K170897	Remake
Safety mechanism-hub	NA	Polycarbonate (PC)		
Protective pad	NA	Polyethylene (PE)		
Biocompatibility	Per ISO 10993-1	Per ISO 10993-1	Per ISO 10993-1	same
Sterilization	EO sterilization	EO sterilization	EO sterilization	Same
SAL	10^{-6}	10^{-6}	10^{-6}	Same
Single use	Single use	Single use	Single use	Same
Endotoxin Limit	20 EU per device	20 EU per device	20 EU per device	Same

Similar 1- Indications for Use

Both the predicate and Huber Needle Infusion Set and Safety Huber Needle Infusion Set are intended for use with a non-coring right angle needle intended for insertion into the septum of a subcutaneously implanted port and for the infusion of fluids and drugs, as well as into the port. Although the Huber Needle Infusion Set has no safety mechanism, the predicate and proposed device have similar Indications for Use, and the same intended use.

Similar 2- Configuration

The Safety Huber Needle Infusion Set and Huber Needle Infusion Set have the similar configuration with the predicate device. Although the Huber Needle infusion Set does not have the safety mechanism, the difference will not affect the safety and effectiveness of the proposed device. Therefore, the difference does not raise new questions on safety and effectiveness of the proposed device.

Different 3- Needle gauge

The needle gauge of proposed device is different from the predicate device. However, the performance of needle has been evaluated and test results demonstrated compliance with related needle performance standards requirements. Therefore, the difference does not raise new questions on safety and effectiveness of the proposed device.

Different 4- Needle length

The needle length of proposed device is different form the predicate device. However, the needle length of the Safety Huber Needle Infusion Set and Huber Needle Infusion Set is within the needle length of the predicate device. Additionally, the performance of the needle has evaluated per ISO 7864 and test results meet related standards requirements. Therefore, the difference does not raise new questions on safety and effectiveness of the

proposed device.

Different 5 - Priming volume
The priming volume of the proposed device is different from the predicate device. The priming volume for each configuration of proposed device is included in the user manual. Therefore, the slight difference on priming volume does not raise new questions on safety and effectiveness of the proposed device.

Different 6 - Safety Mechanism Design
The proposed Huber Needle Infusion Set does not have a safety mechanism. The safety mechanism design of proposed Safety Huber Needle Infusion Set is different from predicate device. However, both the proposed device and predicate device were tested in simulated clinical use study. The test results showed the safety mechanism can protect the needle tip from exposure. And there's a click sound for the user to know when the needle is locked. Therefore, the difference does not raise new questions on safety and effectiveness of the proposed device.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

Performance Testing

Functional performance testing was completed to demonstrate that the proposed device performs as intended after ethylene oxide (EO) sterilization. The following performance tests were evaluated in support of the substantial equivalence determination:

Wing Flexibility	Verify whether wings are able to withstand bending without cracking
Penetration Force	ISO 10555-6:2015 *Intravascular catheters – Sterile and single-use catheters Part 6: Subcutaneous implanted ports*
Coring Testing	ASTM F3212-16: *Standard test method for coring testing of Huber needles*
Occlusion Testing	Verify that the device can understand 45 psi pressure, and the liquid path is freedom from leakage
Leakage, Joint integrity, tubing testing, tensile strength	ISO 8536-4:2010 *Infusion equipment for medical use- Part 4: Infusion sets for single use, gravity feed*
Safety Mechanism	ISO 23908:2011 *Sharps injury protection – Requirements and test*

Activation and Function	*methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood Sampling*; FDA Guidance Medical Devices with Sharps Injury Prevention Features, Issued August 9, 2005
Ability to withstand power injection pressures	Watertight and resistant up to a high pressure of 330 psi
Power Injection Flow rate	Confirm Maximum flow rates with a power injector
Needle performance	ISO 7864:2016 *Sterile Hypodemic Needles for Single Use- Requirements And Test Methods*; ISO 9626:2016 *Stainless Steel Needle Tubing For The Manufature of Medical Devices- Requirements and Test Methods*
Luer Connector performance	ISO 80369-7:2016 *Small-bore connectors for liquids and gases in healthcare applications-Part 7: Connectors for intravascular or hypodermic applications*; ISO 80369-20:2015 *Small-bore connectors for liquids and gases in healthcare applications-Part 20: Common test methods*
MRI Compatibility	ASTM F2182-09 *Standard test method for measurement of radio frequency induced heating on or near passive implants during magnetic resonance imaging*; ASTM F2052-06 *Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment*; ASTM 2119-07 *Standard test method for evaluation of MR image artifacts from passive implants*; ASTM 2213-06 R11 *Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment*
Simulated Use Study	FDA Guidance Medical Devices with Sharps Injury Prevention Features, Issued August 9, 2005
Particulates	USP <788>
Sterilization	ISO 10993-7:2008 *Biological Evaluation of Medical Device- Part 7: Ethylene Oxide Sterilization Residuals* ASTM F1886 / F1886M-16, *Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection* ASTM F88/F88M-15, *Standard Test Method For Seal Strength Of Flexible Barrier Materials. (Sterility)* ASTM F1929-15 *Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration*

Biocompatibilty testing

The materials of construction of a fully assembled Huber Needle Infusion Set and Safety Huber Needle Infusion Set were tested according to ISO 10993-1:2018. The following biocompatibility testing was performed with the reference standard:

Biocompatibility Testing	Standard
Cytotoxicity	ISO 10993-5
Skin Sensitization	ISO 10993-10
Intracutaneous Reactivity	ISO 10993-10
Acute Systemic Toxicity	ISO 10993-11
Pyrogen	ISO 10993-11, USP 42 NF 37 <151>
Hemolytic Property	ASTM F756
Partial Thromboplastin	ASTM F2382
Complement Activation	ISO 10993-4
Bacterial Endotoxin Limit	USP <85>

8. Clinical Test Conclusion

No clinical study is included in this testing.

9. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device, K200463, the Huber Needle Infusion Set and the Safety Huber Needle Infusion Set are as safe and effective for its intended use and substantially equivalent to the predicate device, K170897.