



June 8, 2023

Promised Hangzhou Meditech Co., Ltd.  
% Wei Shan Hsu  
Regulatory Manager  
Vee Care (Asia) Limited  
17th Chung Pont Commercial Building  
300 Hennessy Road, Hong Kong, Hong Kong CHN

Re: K230715

Trade/Device Name: Promised Safety Huber Needle  
Regulation Number: 21 CFR 880.5570  
Regulation Name: Hypodermic Single Lumen Needle  
Regulatory Class: Class II  
Product Code: PTI  
Dated: May 11, 2023  
Received: May 12, 2023

Dear Wei Shan Hsu:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



CAPT Alan Stevens  
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

## Indications for Use

510(k) Number (if known)

K230715

Device Name

Promised Safety Huber Needle

Indications for Use (Describe)

The needle is used to access surgically implanted vascular ports.

Safety Huber Needles 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 sheathing the needle. This device is for adult use only.

In addition, when used with ports that are indicated for power injection of contrast media into the central venous system, the high pressure resistant model is indicated for high-pressure injection of contrast media for CT imaging.

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

## 1 Date Prepared

June 8th, 2023

## 2 Submitter's Information

**Name of Sponsor:**

Promisemed Hangzhou Meditech Co., Ltd.

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## 3 Trade Name, Common Name, Classification

**Trade/Product Name:** Promisemed Safety Huber Needle

**Regulation name:** Hypodermic Single Lumen Needle

**Regulation Number:** 21 CFR 880.5570

**Device Class:** Class II

**Product Code:** PTI

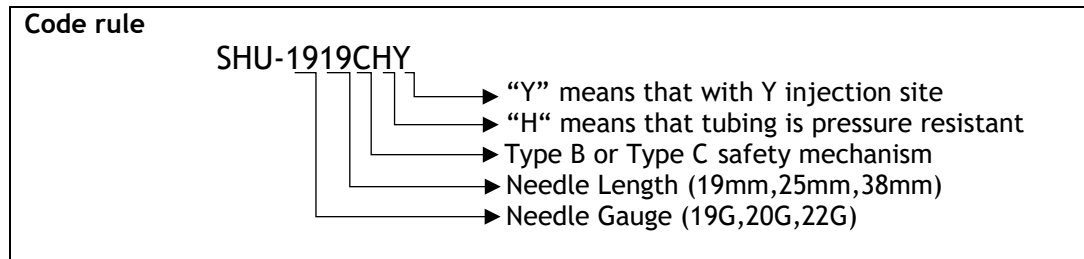
## 4 Identification of Predicate Device

K170897 Surecan Safety II

## 5 Description of the Device

Safety Huber Needle 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 sheathing the needle.

The device includes an integrated extension set consisting of a Huber needle and safety mechanism (Type B and Type C), needle infusion tubing (pressure resistance or non-pressure resistance), Y-injection site, clamp and female Luer lock adapter. The pressure resistance tubing can be used for power injection up to 330 psi. The device will be retained on patient for 24h to 7 days.



**Table 1. Model list**

Type	Model	Note	Gauge	Color
Type B	SHU-1919B, SHU-1925B, SHU-1938B	NA	19G	Cream
	SHU-1919BH, SHU-1925BH, SHU-1938BH	Pressure resistance up to 330 psi		
	SHU-1919BY, SHU-1925BY, SHU-1938BY	With Y-injection site		
	SHU-1919BHY, SHU-1925BHY, SHU-1938BHY	Pressure resistance up to 330 psi with Y-injection site		
	SHU-2019B, SHU-2025B, SHU-2038B	NA	20G	Yellow
	SHU-2019BH, SHU-2025BH, SHU-2038BH	Pressure resistance up to 330 psi		
	SHU-2019BY, SHU-2025BY, SHU-2038BY	With Y-injection site		
	SHU-2019BHY, SHU-2025BHY, SHU-2038BHY	Pressure resistance up to 330 psi with Y-injection site		
	SHU-2219B, SHU-2225B, SHU-2238B	NA	22G	Black
	SHU-2219BH, SHU-2225BH, SHU-2238B	Pressure resistance up to 330 psi		
	SHU-2219BY, SHU-2225BY, SHU-2238BY	With Y-injection site		
	SHU-2219BHY, SHU-2225BHY, SHU-2238BHY	Pressure resistance up to 330 psi with Y-injection site		
Type C	SHU-1919C, SHU-1925C, SHU-1938C	NA	19G	Cream

SHU-1919CH, SHU-1925CH, SHU-1938CH	Pressure resistance up to 330 psi		
SHU-1919CY, SHU-1925CY, SHU-1938CY	With Y-injection site		
SHU-1919CHY, SHU-1925CHY, SHU-1938CHY	Pressure resistance up to 330 psi with Y-injection site		
SHU-2019C, SHU-2025C, SHU-2038C	NA	20G	Yellow
SHU-2019CH, SHU-2025CH, SHU-2038CH	Pressure resistance up to 330 psi		
SHU-2019CY, SHU-2025CY, SHU-2038CY	With Y-injection site		
SHU-2019CHY, SHU-2025CHY, SHU-2038CHY	Pressure resistance up to 330 psi with Y-injection site		
SHU-2219C, SHU-2225C, SHU-2238C	NA	22G	Black
SHU-2219CH, SHU-2225CH, SHU-2238CH	Pressure resistance up to 330 psi		
SHU-2219CY, SHU-2225CY, SHU-2238CY	With Y-injection site		
SHU-2219CHY, SHU-2225CHY, SHU-2238CHY	Pressure resistance up to 330 psi with Y-injection site		

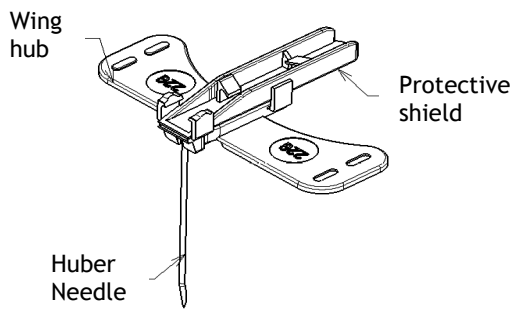


Figure 1. Type B

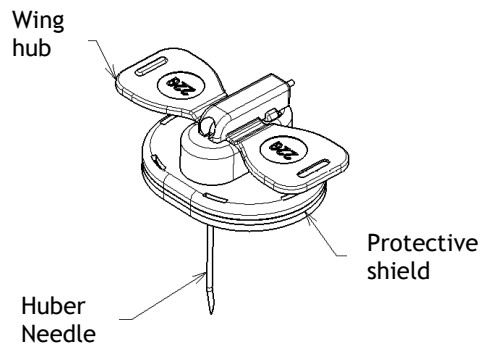


Figure 2. Type C

## 6 Indication

The needle is used to access surgically implanted vascular ports.

Safety Huber Needles 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 sheathing the needle. This device is for adult use only.

In addition, when used with ports that are indicated for power injection of contrast media into the central venous system, the high pressure resistant model is indicated for high-pressure injection of contrast media for CT imaging.

## 7 Similarities and Differences of the Proposed Devices to the Predicate Devices

The Promised Safety Huber Needle is substantially equivalent to the predicate device, Surecan Safety II (K170897) in that these devices have similar intended use and technological characteristics. The basic technological and operating principles are the same for both devices. Both the subject and predicate devices are disposable, sterile, single patient use devices. The differences between the subject device and predicate device do not raise new questions of safety and effectiveness.

A detailed comparison to the predicate is provided in Table 1.

	Subject Device	Predicate Device (K170897)	Comments
Trade Name	Promised Safety Huber Needle	Surecan Safety II	
Manufacturer	Promised Hangzhou Meditech Co., Ltd	B. Braun Medical Inc	
Device Class	Class II	Class II	Same
Product Code	PTI	PTI	Same
Regulation number	880.5570	880.5570	Same
Regulation Name	Hypodermic Single Lumen Needle	Hypodermic Single Lumen Needle	Same
Intended Use	It is used to access surgically implanted vascular ports and is indicated for use in the administration of fluids and drugs.	Access surgically implanted vascular ports for the infusion of fluids, drugs, and blood sampling	Similar <sup>1</sup>  The subject device is not intended for blood sampling.
Indications for Use	The needle is used to access surgically implanted vascular ports. Safety Huber Needles 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 sheathing the needle. This device is for adult use only. In addition, when used	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.	Similar <sup>2</sup>  The subject device is not intended for blood sampling.

	with ports that are indicated for power injection of contrast media into the central venous system, the high pressure resistant model is indicated for high-pressure injection of contrast media for CT imaging.	When used with ports that are 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.	
Safety Mechanism Design	Manually activated safety mechanism upon removal of the needle from the implanted vascular port.  Safety mechanism either have a protective shield cover the needle tip (Type B, figure1) or locks needle into place when a firm stop is felt (Type C).	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.	Similar <sup>3</sup>  The subject device has additional type of safety mechanism (Type B, refer to Table1 and Figure 1)
Do any sets contain an Injection Site / Luer Access Device?	Yes	Yes	Same
Needle bevel design	Non-coring angled needle	Non-coring angled needle	Same
Needle Size	19G,20G,22G	19G,20G,22G	Same
Needle Length	19mm (0.75 inch) 25 mm (1.0 inch) 38mm (1.5 inch)	0.5 inch 0.6 inch 0.8 inch 1.0 inch 1.3 inch 1.5 inch	Different <sup>4</sup>  Predicate device has wider range.
Available for use with contrast media?	Yes for "H" subtype (refer to Table 1)	Yes	Same
Does the device have wings?	Yes	Yes	Same
Reuse durability	Single use	Single use	Same
Ability to withstand power injection pressures	330 psi ("H" subtype)	325 psi	Similar <sup>5</sup>
Flow rates (Pressure injection)	19, 20 gauge - 5mL/s  22 gauge - 2 mL/s	19, 20 gauge - 5mL/s  22 gauge - 2 mL/s	Same
Biocompatibility	Complied with ISO10993 series standards, and the	Complied with ISO10993 series standards, and the	Similar <sup>6</sup>  The subject device conducted



	<p>following tests are performed</p> <ul style="list-style-type: none"> <li>- Cytotoxicity: No cytotoxicity</li> <li>- Skin Irritation: No evidence of skin irritation</li> <li>- Skin Sensitization: No evidence of sensitization</li> <li>-Acute and Subchronic Systemic Toxicity: No systemic toxicity</li> <li>-Hemolysis: No evidence of hemolysis</li> <li>-Implantation: No abnormal symptoms at the implantation site</li> <li>- Genotoxicity: No evidence of mutagenicity</li> <li>-Pyrogen: Non pyrogenic</li> </ul>	<p>following tests are performed</p> <ul style="list-style-type: none"> <li>- Cytotoxicity: No cytotoxicity</li> <li>- Skin Irritation: No evidence of skin irritation</li> <li>- Skin Sensitization: No evidence of sensitization</li> <li>-Acute and Subchronic Systemic Toxicity: No systemic toxicity</li> <li>- Hemocompatibility: No evidence of hemolysis</li> <li>-Pyrogen: Non pyrogenic</li> </ul>	<p>additional tests, i.e. implantation test and genotoxicity test</p>
Configuration and Materials	<ol style="list-style-type: none"> <li>1.Huber needle: X5CrNi18-10</li> <li>2.Tubing: TPU</li> <li>3.Luer lock connector: Copolyester</li> <li>4.Y-injection site: Copolyester and silicon</li> <li>5.Protective base: Foam and Copolyester</li> <li>6.Wing hub/Protective shield: PP</li> <li>7.Clamp: POM</li> <li>8.Cap/Needle Sheath: PE</li> </ol>	Unknown	<p>Unknown<sup>7</sup></p> <p>The material's biosafety is addressed through biocompatibility testing per ISO 10993.</p>
Performance	<p>Complied with ISO 80369-7:2021, ISO8536-4:2019, ISO 23908, ISO 9626:2016, ISO 7864:2016, ANSI/AAMI CN27:2021, ASTM F3212-16</p>	<p>Complied with ISO 594-2:1998, ISO 8536-4:2010, ISO 23908:2011, ISO 9626:1991, JIS T3221:2011</p>	<p>Similar<sup>8</sup></p> <p>The ISO 594-2:1998 has been replaced by ISO 80369-7:2021.</p> <p>The subject device meets the requirement of</p>

			FDA recognized standards.
Sterilization method and SAL	EO Sterilization SAL = $10^{-6}$	EO Sterilization SAL = $10^{-6}$	Same

### Discussions of differences in technological characteristics

The subject device has the similar intended use, indications for use, technological characteristics, safety mechanism design when compared to the predicate device. The basic technological and operating principles are the same for both devices. Both the subject and predicate devices are disposable, sterile, single patient use devices.

Note 1 and 2: The subject device is not intended for blood sampling, this difference does not affect the substantial equivalence of the device.

Note 3: The subject device has additional type of safety mechanism (Type B, Figure 1) to protect against sharps injury. The sharps protection feature is addressed through testing per ISO23908.

Note 4: The needle length of subject device is within the range of predicate device. The difference needle length does not affect the substantial equivalence of the device.

Note 5: The “H” subtype (refer to Table 1) of subject device withstands power injection pressures of 330 psi, which is higher than predicate device. The flow rate under 330 psi has been verified.

Note 6 and 7: The biocompatibility tests conducted demonstrated the safety of subject device.

Note 8: The subject device meets the requirements of FDA recognized standards.

The differences above do not impact the substantial equivalence of the device.

## 8 Performance Testing Summary

The bench testing performed verifies that the performance of the subject device is substantially equivalent in terms of critical performance characteristics to the predicate device. These tests include:

- ISO 8536-4 :2019 Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed
- ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications
- ISO 23908:2011, 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 9626:2016, Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
- ISO 7864:2016, Sterile hypodermic needles for single use – Requirements and test methods
- ANSI/AAMI CN27:2021 General Requirements For Luer Activated Valves (LAVs) Incorporated Into Medical Devices For Intravascular Applications
- ASTM F3212-16 Standard Test Method for Coring Testing of Huber Needles
- Power injection flow rate testing (non-standardized test)
- USP<85> Bacterial Endotoxin Test

#### Biocompatibility

In accordance with ISO 10993-1 the device is classified as External communicating device, in contact with circulating blood with prolonged duration. The biosafety tests that required consideration were validated:

- ISO 10993-5:2009 - Biological Evaluation of Medical Devices -- Part 5:Tests for in Vitro Cytotoxicity
- ISO 10993-10:2010 - Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity-Acute and Subchronic systemic toxicity
- ISO 10993-3:2014 - Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity-Genotoxicity Test

- ISO 10993-4:2017, Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
- ISO 10993-6:2016 - Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
- ISO 10993-7:2008, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
- USP NF 2021 chapter <151> Pyrogen Test
- USP<788> Particulate matter in injections

#### Sterility, Shipping, and Shelf-Life

- ISO 11135:2014, Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices
- Sterile Barrier Packaging Testing performed on the proposed device:
  - Seal strength ASTM F88/F88-15
  - Dye penetration ASTM F1929-15
  - Sterility test USP39 <71>
- Shelf life of 3 years is validated using the FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

## 9 Conclusion

Based on the information provided within this 510(k) submission, the differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The proposed subject device is substantially equivalent to the predicate device and is as safe and as effective as the legally marketed predicate device.