February 15, 2023

Promisemed Hangzhou Meditech Co., Ltd.
Zearou Yang
Regulatory Affairs Manager
No. 1388 Cangxing Street, Cangqian Community
Yuhang District
Hangzhou City, Zhejiang 311121
China

Re: K222271
Trade/Device Name: Verisafe Safety sterile needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Needle, hypodermic, single lumen
Regulatory Class: Class II
Product Code: FMI
Dated: December 14, 2022
Received: December 14, 2022

Dear Zearou Yang:

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,

Alan M. Stevens -S3

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

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)*
K222271

Device Name

Verisafe Safety Sterile Needles

Indications for Use *(Describe)*

It is intended for use in the aspiration and injection of fluids for medical purposes. When the safety shield is manually activated, it will cover the needle immediately after use to minimize risk of accidental needle stick.

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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K222271 510k Summary

1. Date Prepared

February 14th, 2023

2. Submitter's Information

Name of Sponsor:

Promisemed Hangzhou Meditech Co., Ltd.

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No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, China

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zearou.yang@promisemed.ca

3. Trade Name, Common Name, Classification

Trade/Product Name: Verisafe Safety sterile needles

Common Name: Safety sterile needles

Classification name: Needle, hypodermic, single lumen

Regulation Number: 880.5570

Device Class: Class II

Product Code: FMI

4. Identification of Predicate Device

K123684: Sol-Care Safety Needle

5. Description of the Device

The Verisafe Safety sterile needles are sterile, single use, standard hypodermic needle with a shield to enclose the needle after use.

The Verisafe Safety sterile needles are for use with syringes.

The device mainly consists of hub, needle, needle cap and safety shield. It is packaged in a

sealed sterility barrier. This is a single-use device and delivered sterile. Sterilization process is validated according to EN ISO 11135. Sterilization process undergoes routine control.

Sterilized by ETO, shelf life 5 years.

6. Indication

It is intended for use in the aspiration and injection of fluids for medical purposes. When the safety shield is manually activated, it will cover the needle immediately after use to minimize risk of accidental needle stick.

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

Promisemed Safety sterile needles are substantially equivalent to the predicate device, Sol-Care Safety Needle, K123684 in that these devices have same 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 affect the basic design principle, usage of the subject device.

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

Items	Subject Device	Predicate Device (K123684)	Comments
Trade Name	Verisafe Safety sterile needles	Sol-Care Safety Needle;	
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd	Sol-Millennium. Medical. Inc.	
Device Class	Class II	Class II	Similar
Product Code	FMI	FMI	Similar
Regulation number	880.5570	880.5570	Similar
Regulation Name	Needle, hypodermic, single lumen	Needle, hypodermic, single lumen	Similar
Intended Use/ Indications for Use	It is intended for use in the aspiration and injection of fluids for medical purposes. When the safety shield is manually activated, it will cover the needle immediately after use to minimize risk of accidental needle stick.	It is intended for use in the aspiration and injection of fluids for medical purposes. When the safety shield is manually activated, it will cover the needle immediately after use to minimize risk of accidental needle stick.	Similar
Operating Principle	When the safety shield is manually activated, it will cover the needle immediately after use to minimize risk of accidental needle stick.	The Sol-Care Safety Needle has a shield that covers the needle point after use. In the activated position, the needle shield guards against accidental needle stick during normal handling and disposal of the used needle/syringe combination.	Similar
Needle Gauge	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	Similar

Needle Length	1/2in, 3/4in, 5/8in, 1in, 1 1/4in, 1 1/2in, 2 in	3/8 in to 1 1/2 in	Different, Subject devices have more needle lengths than predicate device.
Needle hub color	Per ISO 6009: Pink/18G, Cream/19G, Yellow/20G, Light green/21G, Black/22G, Light blue/23G, Medium purple /24G, Orange /25G, Brown /26G, Medium grey /27G, Blue - green /28G, Red /29G, Yellow /30G.	Per ISO 6009: Pink/18G, Cream/19G, Yellow/20G, Light green/21G, Black/22G, Light blue/23G, Medium purple /24G, Orange /25G, Brown /26G, Medium grey /27G, Blue - green /28G, Red /29G, Yellow /30G.	Each color is in accordance with ISO [i]6009.
Reuse durability	Single Use	Single Use	Similar
Biocompatibility	Complied with ISO10993 series standards, and the following tests are performed - Cytotoxicity: No cytotoxicity - Intracutaneous Reactivity No evidence of irritation - Skin Sensitization: No evidence of sensitization - Acute Systemic Toxicity: No systemic toxicity - Pyrogen: Non pyrogenic - Platelet Count: No effect - Hemolysis： No effect	Per ISO 10993-1	Similar
Materials	- Needle: Stainless Steel (06Cr19Ni10) - Hub: Polypropylene (PP) - Need Cap: Polypropylene (PP)	- Needle: Stainless Steel (06Cr19Ni10) - Hub: Polypropylene (PP) - Need Cap: Polypropylene (PP)	Similar
Performance	Complied with ISO 7864, ISO 9626, ISO 80369-7	Complied with ISO 7864, ISO 9626, ISO 80369-7	Similar
Sterilization method	EO Sterilization	EO Sterilization	Similar

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 and standard are provided in Table 2 and Table 3.

- **Table 2 Performances**

No.	Test item	Reference recognized standards
1.	1.1 Appearance	EN ISO 7864:2016, Sterile hypodermic syringes for single use – Requirements and test methods
	1.2 Cleanliness	

2.	Color code	EN ISO 6009:2016, Hypodermic needles for single use - Colour coding for identification
3.	3.1 Dimensions	EN ISO 7864:2016, Sterile hypodermic syringes for single use – Requirements and test methods
		EN ISO 9626:2016, Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
	3.2 Length of the needle	EN ISO 7864:2016, Sterile hypodermic syringes for single use – Requirements and test methods
4.	Lubricant	EN ISO 7864:2016, Sterile hypodermic syringes for single use – Requirements and test methods
5.	Needle point	EN ISO 7864:2016, Sterile hypodermic syringes for single use – Requirements and test methods
6.	Penetration force	EN ISO 7864:2016, Sterile hypodermic syringes for single use – Requirements and test methods
7.	Bond between needle and hub	EN ISO 7864:2016, Sterile hypodermic syringes for single use – Requirements and test methods
8.	Patency of lumen	EN ISO 7864:2016, Sterile hypodermic syringes for single use – Requirements and test methods
9.	Needle cap	/
10.	10.1 Stiffness	EN ISO 9626:2016, Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
	10.2 Resistance to breakage	EN ISO 9626:2016, Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
	10.3 Resistance to corrosion	EN ISO 9626:2016, Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
11.	11.1 Safety feature (Activate force)	EN ISO 23908:2013, Sharps injury protection— Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
	11.2 Safety feature (Reuse Prevention)	EN ISO 23908:2013, Sharps injury protection— Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
	11.3 Safety feature (Safety Performance)	EN ISO 23908:2013, Sharps injury protection— Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
12.	12.1 Dimension	ISO 80369-7:2021, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications

	12.2 Positive pressure liquid leakage	ISO 80369-7:2021, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
	12.3 Sub atmospheric pressure air leakage	ISO 80369-7:2021, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
	12.4 Stress cracking	ISO 80369-7:2021, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
	12.5 Resistance to separation from axial load	ISO 80369-7:2021, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
	12.6 Resistance to separation from unscrewing	ISO 80369-7:2021, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
	12.7 Resistance to overriding	ISO 80369-7:2021, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
13.	Particulate contamination	USP 39 <788> Particulate matter in injections
14.	Acidity and alkalinity	EN ISO 7864:2016, Sterile hypodermic syringes for single use – Requirements and test methods
15.	Extractable metals	EN ISO 7864:2016, Sterile hypodermic syringes for single use – Requirements and test methods
16.	Package appearance	ASTM F1886/F1886M – 16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
17.	Seal strength	EN 868-5:2018 Packaging for terminally sterilized medical devices Part 5: Sealable pouches and reels of porous materials and plastic film construction – Requirements and test methods
18.	Dye penetration	ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
19.	Sterility	USP 39 <71> Sterility tests
20.	Bacterial endotoxin	USP 40 <85> Bacterial endotoxins test

- **Table 3 Biocompatibility**

No.	Test item	Reference recognized standards
1.	In Vitro Cytotoxicity – MTT Method, MEM with 10% FBS extract	ISO 10993-5:2009 – Biological Evaluation of Medical Devices -- Part 5: Tests for in Vitro Cytotoxicity
2.	Skin Sensitization – Guinea Pig Maximization, 0.9% sodium chloride extract and sesame oil extract	ISO 10993-10:2021, Biological Evaluation of Medical Devices -- Part 10: Tests for Irritation and Skin Sensitization

3.	Intradermal reaction test, 0.9% sodium chloride extract and sesame oil extract	ISO 10993-23:2021, Biological evaluation of medical devices - Part 23: Tests for irritation
4.	Acute systemic toxicity 0.9% sodium chloride extract and sesame oil extract	ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity- Acute systemic toxicity and pyrogen test
5.	Pyrogen study in rabbits 0.9% sodium chloride injection	ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity- Acute systemic toxicity and pyrogen test USP43-NF37<151> Pyrogen Test
6.	In Vitro Hemolytic Properties Test	ASTM F756-17 Standard Practice for Assessment of Materials
7.	Ethylene Oxide residues EO ECH Test	ISO 10993-7:2008, Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals

9. Conclusion

The comparison of intended use, technological characteristics, and performance data of the subject device has demonstrated substantial equivalence to the predicate device.