September 28, 2023

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

Re: K231792
Trade/Device Name: VeriSafe Safety sterile syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, MEG
Dated: August 29, 2023
Received: August 30, 2023

Dear Wei 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
Director
DHT3C: Division of Drug Delivery and
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and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
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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)*
K231792

Device Name
VeriSafe Safety Sterile Syringes

Indications for Use *(Describe)*
It is intended to inject fluids into the body or withdraw blood for medical purposes. After injection, the needle tube will be retracted into the barrel when the safety features are manually activated to minimize the risk of accidental sharps injury.

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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K231792-510(K)Summary

1 Date Prepared

September 18, 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: VeriSafe Safety sterile syringes

Common Name: Piston Syringe

Classification name: Syringe, Piston; Syringe, Antistick

Regulation Number: 21 CFR 880.5860

Device Class: Class II

Product Code: FMF, MEG

4 Identification of Predicate Device

K213560 Verifine Safety Syringe with Fixed Needle

5 Description of the Device

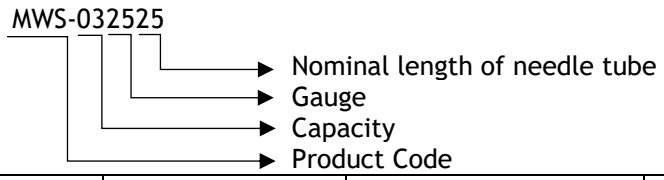
Safety Sterile Syringes is a sterile device consisting of a calibrated barrel, plunger, piston, push button, retraction cylinder, sealing ring, spring and a needle. It is made of plastic, stainless steel and silicone materials. Safety Sterile Syringes have two types: Type F and type D. Type F is a syringe with a fixed needle. Type D is a syringe with a detachable needle. The detachable needle is secured by rotating it through the front needle hub into the back needle hub located on the syringe.

Safety Sterile Syringes is using plunger to fill syringe as well as discharge the fluid. After use, by continuing to press the push-button down to depress the plunger all of the way within the barrel, the safety mechanism will be triggered, then the needle tube, needle hub and retraction cylinder will be retracted into the barrel completely under the force of the spring to minimize the risk of accidental sharps injury.

Product is delivered sterile. Sterilization process is validated according to EN ISO 11135.

This is a single-use device. Safety Sterile Syringes is intended to be used in professional healthcare facility/hospital and transport environment.

Coding rule:



Type	Capacity	Gauge	Nominal length of needle tube	Wall
Type D Type F	1mL,2mL, 3mL,5mL,10mL	18G, 20G, 22G, 23G, 25G, 27G,28G, 29G, 30G, 31G, 32G	6mm,8mm,12mm, 25mm,38mm	Regular wall (RW) Thin wall (TW)

6 Indication

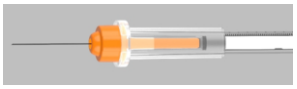
It is intended to inject fluids into the body or withdraw blood for medical purposes. After injection, the needle tube will be retracted into the barrel when the safety features are manually activated to minimize the risk of accidental sharps injury.

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

The VeriSafe Safety sterile syringe is substantially equivalent to the predicate device, Verifine Safety Syringe with Fixed Needle (K213560) in that these devices have same intended use and technological characteristics. Using plunger to fill syringe as well as discharge the fluid is the technological principle of both the subject device and predicate device. The needle of both devices is made of stainless steel (X5CrNi18-10). The performance of both devices fulfills the requirement of ISO 7886-1, ISO 9626, ISO 7864 and ISO 23908. Both the subject and predicate devices are disposable, EO sterilized, single patient use devices. Both the subject and predicate device are used in Professional healthcare facility and transport environment.

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

	Subject Device	Predicate Device (K213560)	Comments
Trade Name	VeriSafe Safety Sterile Syringes	Verifine Safety Syringe with Fixed Needle	
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd	Promisemed Hangzhou Meditech Co., Ltd	
Device Class	Class II	Class II	Same
Product Code	FMF, MEG	FMF, MEG	Same
Regulation number	880.5860	880.5860	Same
Regulation Name	Piston syringe	Piston syringe	Same
Intended Use/ Indications for Use	It is intended to inject fluids into the body or withdraw blood for medical purposes. After injection, the needle tube will be retracted into the barrel when the safety features are manually activated to minimize the risk of accidental sharps injury.	It is intended to inject fluids into or withdraw fluids from the body for medical purposes.	Same
Operating Principle	Plunger is used to fill syringe as well as discharge the fluid. After use, the needle tube will be retracted into the barrel by pressing the push-button to depress the plunger all of the way within the barrel.	Plunger is used to fill syringe as well as discharge the fluid. The protective shield will permanently be locked in place by pulling forward till click, providing protection against needle sticks.	Different- See Comment #1
Safety mechanism	The safety mechanism is activated by pressing the push-button down to depress the plunger all of the way within	The safety mechanism is activated by pushing the sliding sleeves. When	Different See Comment#2

	the barrel. When activated, needle is retracted into the barrel.	activate, needle is covered by sliding sleeves.	
Volume	1mL,2mL, 3mL,5mL,10mL	0.5ml,1.0ml	Different See Comment #3
Tip type	Fixed Needle and detachable needle	Fixed Needle	Different See Comment #4
Needle and syringe tip configuration	Type F  Type D 		Different See Comment #5
Gauge	18G, 20G, 22G, 23G, 25G, 27G,28G, 29G, 30G, 31G, 32G	21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G	Different See Comment #6
Needle Length	6mm,8mm,12mm, 25mm,38mm	12mm, 16mm, 25 mm, 32mm, 38mm	Different See Comment #7
Gradations legibility	Legible	Legible	Same
Lubricant	Silicone oil	Silicone oil	Same
Barrel transparency	Transparent	Transparent	Same
Reuse durability	Single Use	Single Use	Same
Biocompatibility	Complied with ISO10993 series standards, and the following tests are performed - Cytotoxicity: No cytotoxicity - Skin Irritation: No evidence of skin irritation - Skin Sensitization: No evidence of sensitization -Acute Systemic Toxicity: No systemic toxicity -Hemolysis: No evidence of hemolysis -Pyrogen: Non pyrogenic -USP <788> Particulate matter	Complied with ISO10993 series standards, and the following tests are performed - Cytotoxicity: No cytotoxicity - Skin Irritation: No evidence of skin irritation - Skin Sensitization: No evidence of sensitization -Acute Systemic Toxicity: No systemic toxicity -Hemolysis: No evidence of hemolysis -Pyrogen: Non pyrogenic -USP <788> Particulate matter	Same

Configuration and Materials	Needle, spring: Stainless Steel (X5CrNi18-10) Barrel/push-button: Polypropylene Plunger: Polypropylene Needle cap: Polypropylene Piston: Nitrile butadiene rubber/Thermoplastic elastomer Retraction cylinder sealing ring: Silicone rubber Needle hub: Polypropylene Needle hub sealing ring: Thermoplastic elastomer Retraction cylinder: Acrylonitrile Butadiene Styrene	Needle: Stainless Steel (X5CrNi18-10) Barrel/push-button: Polypropylene Plunger: Polypropylene Needle cap: Polyethylene Piston: Polyisoprene rubber Sliding Sleeve, Cover: Polypropylene Plunger stopper, Tight ring: Acrylonitrile Butadiene Styrene	Similar See Comment# 8
Performance	Complied with ISO 7886-1, ISO 9626, ISO 7864, ISO 23908	Complied with ISO 7886-1, ISO 9626, ISO 7864, ISO 23908	Same
Sterilization method and SAL	EO Sterilization SAL = 10^{-6}	EO Sterilization SAL = 10^{-6}	Same
Environment of use	Professional healthcare facility and transport environment.	Professional healthcare facility and transport environment.	Same
shelf life	3 years	5 years	Different[9] See Comment# 9

Discussions of differences in technological characteristics

Comment #1 and #2 : The subject device has different safety mechanisms to protect against sharps injury. The sharps protection feature of both devices are addressed through testing per ISO 23908. The difference in sharps protection feature does not affect the effectiveness and safety of the device.

Comment #3 : The subject device has a different capacity range. The specification of capacity of both devices fulfils the requirement of ISO 7886-1. The difference in capacity does not affect the effectiveness and safety of the device.

Comment # 4 : The subject device has an additional type of detachable needle tip. The performance of detachable needle type fulfils the requirement of ISO 9626:2016, ISO 7864:2016 and ISO 7886-1. The difference in tip type does not affect the effectiveness and safety of the device.

Comment # 5: Needle and syringe tip configuration of the subject device is different from that of predicate device. The performance of the subject device fulfill the requirements of ISO 9626:2016, ISO 7886-1:2016, ISO 7864:2016, ISO 23908:2011. The difference in needle and syringe tip configuration does not affect the effectiveness and safety of the device.

Comment #6 and #7 : The gauge and needle length of the subject device is different from the predicate device. The specification of gauge and needle length of both devices fulfil the requirement of ISO 9626:2016 and ISO 7864:2016. The difference in gauge and needle length does not affect the effectiveness and safety of the device.

Comment #8: The syringe bodies of subject device and predicate device have material differences. The biocompatibility tests conducted demonstrated the safety of the subject device. The difference in materials does not affect the effectiveness and safety of the device.

Comment # 9 : The subject device has shorter shelf life. The performance of aged subject device has been validated in accordance with ASTM F1980-16, ISO 9626:2016, ISO 7886-1:2016, ISO 7864:2016, ISO 23908:2011. The difference in shelf life does not affect the effectiveness and safety of the device.

The differences above between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question

is raised regarding effectiveness and safety. The subject device is substantially equivalent to the identified predicate 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 7886-1:2017, Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
  - Extraneous matter, Limits for acidity or alkalinity, Limits for extractable metals, Lubrication, Tolerance on graduated capacity, Graduated Scale, Numbering of Scales, Overall length of scale to Nominal capacity line, Position of scale, Barrel, Plunger stopper/ plunger assembly, Nozzle, Dead space, Freedom from air and liquid leakage past plunger stopper, Force to operate the piston, Fit of the plunger stopper/plunger in barrel.
- ISO 9626:2016, Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
  - Stiffness, Resistance to breakage, Resistance to corrosion
- ISO 7864:2016, Sterile hypodermic needles for single use — Requirements and test methods
  - Cleanliness, Colour coding, Needle tube-Outside diameter, Tolerance on length,Freedom from defects, Needle points, Fragmentation test, Penetration force and drag force, Bond between hub and needle tube, Patency od lumen
- 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
  - Safety mechanism activation, Safety overriding and unlocking force after activation, Simulated clinical Use
- USP<85> Bacterial Endotoxin Test

Biocompatibility

In accordance with ISO 10993-1 the device is classified as Externalcommunicating device, Blood path, indirect, with limited contactduration (≤ 24h). 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 10993-10:2021 – Biological Evaluation of Medical Devices -- Part 10: Tests for Skin Sensitization
- ISO 10993-23:2021 – Biological Evaluation of Medical Devices –Part 23: Test for irritation
- ISO 10993-11:2017- Biological evaluation of medical devices - Part 11: Tests for systemic toxicity-Acute systemic toxicity
- ASTM F756-17- Standard practice for assesment of hemolytic properties of materials
- ISO 10993-7:2008- Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
- USP42-NF37<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
- Package integrity testing, after environmental conditioning and simulated transportation in accordance with ASTM D4169-16, was conducted on the final, packaged, and sterile devices. All packaging deemed acceptable for protection of product and sterility maintenance.
- Sterile Barrier Packaging Testing performed on the proposed device:
  - Seal strength ASTM F88/F88-15
  - Dye penetration ASTM F1929-15
  - Sterility test USP38-NF33_C71
- 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.