



April 5, 2022

Promised 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: K213560

Trade/Device Name: Verifine Safety Syringe with Fixed Needle  
Regulation Number: 21 CFR 880.5860  
Regulation Name: Piston Syringe  
Regulatory Class: Class II  
Product Code: FMF, MEG  
Dated: March 17, 2022  
Received: March 17, 2022

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

Sincerely,

CAPT Alan M. 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)

K213560

Device Name

Verifine Safety Syringe with Fixed Needle

Indications for Use (Describe)

It is intended to inject fluids into or withdraw fluids from the body for medical purposes.

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 510(k) Summary

### 1 Date Prepared

April 3rd, 2022

### 2 Submitter's Information

**Name of Sponsor:**

Promisemed Hangzhou Meditech Co., Ltd.

**Address:**

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

**Contact Name:**

Zearou Yang

**Telephone No.:**

+86 571 88772985

**Fax No.:**

+86 571 88772985

**Email Address:**

[zearou.yang@promisemed.ca](mailto:zearou.yang@promisemed.ca)

### 3 Trade Name, Common Name, Classification

**Trade/Product Name:** Verifine Safety Syringe with Fixed Needle

**Common Name:** Piston Syringe

**Classification name:** Piston Syringe

**Regulation Number:** 21 CFR 880.5860

**Device Class:** Class II

**Product Code:** FMF, MEG

### 4 Identification of Predicate Device

K211242; Sterile Hypodermic Syringes

## 5 Description of the Device

Verifine Safety Syringe with Fixed Needle is a sterile device consisting of a calibrated barrel with plunger and a fixed needle at the distal end.

It is made of plastic and silicone materials.

It includes an attached needle with a safety mechanism. The protective shield covers the needle. After injection, the shield is permanently locked in place by pushing axially until a click is heard, reducing risk of needle sticks and rendering the device unusable.

It can be used by health care personnel.

This is a single-use device.

Capacity	Gauge	Needle Length	Packaging Configuration
0.5 ml	28G	12mm, 16mm, 25mm, 32mm, 38mm	Polypropylene/ Polyethylene composite membrane (XPP-B) and Dialyzer paper
	27G	12mm, 16mm, 25mm, 32mm, 38mm	
	26G	12mm, 16mm, 25mm, 32mm, 38mm	
	25G	12mm, 16mm, 25mm, 32mm, 38mm	
	24G	12mm, 16mm, 25mm, 32mm, 38mm	
	23G	12mm, 16mm, 25mm, 32mm, 38mm	
	22G	12mm, 16mm, 25mm, 32mm, 38mm	
1.0 ml	21G	12mm, 16mm, 25mm, 32mm, 38mm	
	28G	12mm, 16mm, 25mm, 32mm, 38mm	
	27G	12mm, 16mm, 25mm, 32mm, 38mm	
	26G	12mm, 16mm, 25mm, 32mm, 38mm	
	25G	12mm, 16mm, 25mm, 32mm, 38mm	
	24G	12mm, 16mm, 25mm, 32mm, 38mm	
	23G	12mm, 16mm, 25mm, 32mm, 38mm	
	22G	12mm, 16mm, 25mm, 32mm, 38mm	
	21G	12mm, 16mm, 25mm, 32mm, 38mm	

## 6 Indication

It is intended to inject fluids into or withdraw fluids from the body for medical purposes.

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

The Verifine Safety Syringe with fixed Needle is substantially equivalent to the predicate device, the Sterile Hypodermic Syringes (K211242) 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 intended use or raise new questions of safety and effectiveness.

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

	Subject Device	Predicate Device (K211242)	
Trade Name	Verifine Safety Syringe with Fixed Needle	Sterile Hypodermic Syringes	Comments
Manufacturer	Promised Hangzhou Meditech Co., Ltd	Promised Hangzhou Meditech Co., Ltd	
Device Class	Class II	Class II	Same
Product Code	FMF, MEG	FMF	Similar  The subject device has additional safety shield to prevent sharp injury.
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 or withdraw fluids from the body for medical purposes.	It is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.	Same
Operating Principle	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.	Plunger is used to fill syringe as well as discharge the fluid.	Different  The subject device has additional safety shield to prevent sharp injury.
Volume	0.5ml, 1.0ml	0.5ml, 1.0ml	Same
Tip type	Fixed Needle	Fixed Needle	Same
Gauge	28G, 27G, 26G, 25G, 24G, 23G, 22G, 21G	28G, 27G, 26G, 25G, 24G, 23G, 22G, 21G	Same
Needle Length	12mm, 16mm, 25 mm, 32mm, 38mm	10mm, 12mm, 16mm, 20mm, 25mm, 32mm, 38mm, 50mm	Different  The needle length range of subject device is within that of predicate device.
Gradations	Legible	Legible	Same

legibility			
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: 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	Needle: Stainless Steel (X5CrNi18-10) Barrel/push-button: Polypropylene Plunger: Polypropylene/ Acrylonitrile Butadiene Styrene Needle cap: Polyethylene/ Polypropylene Piston: Polyisoprene rubber	The needle of both devices is made of stainless steel. The syringe bodies of subject device and predicate device have material differences. Differences are addressed through biocompatibility testing per ISO 10993.
Performance	Complied with ISO 7886-1, ISO 9626, ISO 7864, ISO 23908	Complied with ISO 7886-1, ISO 9626, ISO 7864	Different The subject device has additional safety shield to prevent sharp injury. The difference is addressed through testing per ISO23908.
Sterilization method and SAL	EO Sterilization SAL = 10 <sup>-6</sup>	EO Sterilization SAL = 10 <sup>-6</sup>	Same

**Discussions of differences in technological characteristics**

-The needle length of subject device is within the range of predicate device. The difference needle length does not affect the effectiveness and safety of the device.

- The syringe bodies of subject device and predicate device have material differences. This difference does not affect the effectiveness and safety of the device. The biocompatibility tests conducted demonstrate the safety of subject device.
- The operating procedure is the same as predicate device. The subject device has additional safety shield to protect against sharps injury. The sharps protection feature is addressed through testing per ISO23908. This difference does not impact the safety and effectiveness 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 7886-1:2017, Sterile hypodermic syringes for single use – Part 1: Syringes for manual use
- 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
- 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
- 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 ( $\leq 24h$ ). 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 10993-10:2010 - Biological Evaluation of Medical Devices -- Part 10: Tests for Irritation and Skin Sensitization



- ISO 10993-11:2006, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity-Acute systemic toxicity
- ISO 10993-4:2017, Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
- 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 5 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.