September 9, 2021

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: K211242
Trade/Device Name: Promisemed Sterile Hypodermic Syringes, Verifine Sterile Hypodermic Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: August 9, 2021
Received: August 9, 2021

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,

For 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K211242

Device Name
Promisemed Sterile Hypodermic Syringes
Verifine Sterile Hypodermic Syringes

Indications for Use *(Describe)*
It is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body.

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
*PRAStaff@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."*

# K211242 510(k) Summary

## 1 Date Prepared

Sep 9th, 2021

## 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

## 3 Trade Name, Common Name, Classification

**Trade/Product Name:** Promisemed Sterile Hypodermic Syringes
Verifine Sterile Hypodermic Syringes

**Common Name:** Sterile Hypodermic Syringes

**Classification name:** Syringe, Piston

**Regulation Number:** 21 CFR 880.5860

**Device Class:** Class II

**Product Code:** FMF

## 4 Identification of Predicate Device

K153537: Sol-M TB Syringe

# 5 Description of the Device

A sterile device consisting of a calibrated barrel with plunger and a fixed needle at the distal end intended to be used for injection/withdrawal of fluids/gas (e.g., medication) to/from a medical device or the body (i.e., capable of both). It is made of stainless steel needle, plastic and silicone materials, and is manually operated. It is intended for various medical applications and is not dedicated to medication administration.

It is intended be used by health-care personnel (doctors, nurses, etc.). The needle is lubricated with silicone. Product is sterile and sterilization process is validated according to ISO 11135:2014.

This is a single-use device without any accessory.

| Capacity | Gauge | Length |
|---|---|---|
| 0.5ml | 28G | 10mm,12mm,16mm,20mm, 25mm,32mm,38mm,50mm |
| | 27G | |
| | 26G | |
| | 24G | |
| | 23G | |
| | 22G | |
| | 21G | |
| 1.0 ml | 28G | 10mm,12mm,16mm,20mm, 25mm,32mm,38mm,50mm |
| | 27G | |
| | 26G | |
| | 24G | |
| | 23G | |
| | 22G | |
| | 21G | |

# 6 Indications for use statement

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

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

The Sterile Hypodermic Syringes is substantially equivalent to the predicate device, the Sol-M TB Syringe (K153537) 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 and usage.

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

| | Subject Device | Predicate Device (K153537) | Comments |
|---|---|---|---|
| Trade Name | Promisemed Sterile Hypodermic Syringes Verifine Sterile Hypodermic Syringes | Sol-M TB Syringe | |
| Manufacturer | Promisemed Hangzhou Meditech Co., Ltd | Sol-Millennium Medical, Inc. | |
| Device Class | Class II | Class II | Same |
| Product Code | FMF | FMF | Same |
| Regulation number | 880.5860 | 880.5860 | Same |
| Regulation Name | Piston syringe | Piston syringe | Same |
| Intended Use/ Indications for Use | It is intended to be used for medical purposes to inject fluids into or withdraw fluids from the body. | 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. | Plunger is used to fill syringe as well as discharge the fluid. | Same |
| 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 | 23G, 26G, 27G | Different<br>Subject device has wider gauge size than predicate device. Differences are addressed through testing per ISO 9626:2016 and ISO 7864:2016. |
| Needle Length | 10mm, 12mm, 16mm, 20mm, 25mm, 32mm, 38mm, 50mm | 1/2” (12.5mm), 3/8” (9.6 mm) | Different<br>Subject device has wider needle length than predicate device. Differences are addressed through |

| | | | |
|---|---|---|---|
| | | | testing per ISO 9626:2016 and ISO 7864:2016. |
| Gradations legibility | Bold markings | Bold markings | Same |
| Lubricant | Silicone | Silicone | 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<br>- Cytotoxicity: No cytotoxicity<br>- Skin Irritation: No evidence of skin irritation<br>- Skin Sensitization: No evidence of sensitization<br>- Acute Systemic Toxicity: No systemic toxicity<br>- Hemolysis: No evidence of hemolysis<br>- Pyrogen: Non pyrogenic<br>- USP <788> Particulate matter | Per ISO 10993-1 | Same |
| Materials | Needle: Stainless Steel (X5CrNi18-10)<br>Barrel: Polypropylene<br>Plunger: Polypropylene/ Acrylonitrile Butadiene Styrene<br>Needle cap: Polyethylene/ Polypropylene<br>Piston: Polyisoprene rubber | Needle: Stainless Steel<br>Barrel: Polypropylene<br>Plunger: Polypropylene<br>Needle cap: Polypropylene<br>Gasket: Santoprene | The needle of both devices is made of stainless steel.<br>The syringe bodies of subject device and predicate device have material differences. Differences are addressed through biocompatility testing per ISO 10993. |
| Performance | Complied with ISO 7886-1, ISO 9626, ISO 7864 | Complied with ISO 7886-1, ISO 9626, ISO 7864 | Same |
| Sterilization method | EO Sterilization | EO Sterilization | Same |

**Discussions of differences in technological characteristics**

- The subject device has wider gauge size and needle length than predicate device. Differences are addressed through testing per ISO 9626:2016 and ISO 7864:2016. The difference in gauge size and needle length does not affect the effectiveness and safety of the device.
- The syringe bodies of subject device and predicate device have material differences. The biocompatibility tests conducted demonstrate the safety of subject device. Difference do not affect the effectiveness and safety 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
- USP<85> Bacterial Endotoxin Test

Sterility, Shipping and Shelf-Life

The sterilization of the product is achieved using ethylene oxide sterilization. Sterilization condition is validated per ISO 11135: 2014 overkill half-cycle approach. The sterility assurance level (SAL) is $10^{-6}$. The amount of ethylene oxide and chlorohydrin residual levels are within the limit and in compliance with ISO 10993-7: 2008 requirement.

The device is non-pyrogenic. Endotoxin is tested per USP<85> and is conducted on every batch. Endotoxin limit for the subject device is less than 20 EU/Device.

- Package integrity testing, after environmental conditioning and simulated transportation in accordance with ASTM D4169, 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 subject device:

  Seal strength ASTM F88/F88-15

  Dye penetration ASTM F1929-15

- 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

- Biocompatibility

  In accordance with ISO 10993-1 the device is classified as External communicating device, Blood path, indirect, with limited contact duration (≤ 24h). The biosafety tests that required consideration were validated:

  a. ISO 10993-5:2009 – Biological Evaluation of Medical Devices -- Part 5: Tests for in Vitro Cytotoxicity
  b. ISO 10993-10:2010 – Biological Evaluation of Medical Devices -- Part 10: Tests for Irritation and Skin Sensitization
  c. ISO 10993-11:2006, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity-Acute systemic toxicity and pyrogen test
  d. USP42-NF37<151> Pyrogen Test
  e. USP<788> Particulate matter in injections
  f. ISO 10993-4:2017, Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood
  g. ISO 10993-7:2008, Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals

# 9 Conclusion

Based on the information provided within this 510(k) submission, the proposed subject device is substantially equivalent to the predicate device and is as safe and as effective as the legally marketed predicate device.