September 8, 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: K210712
Trade/Device Name: Verifine Mechanical Safety Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, FMI
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,

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)*
K210712

Device Name
Verifine Mechanical Safety Insulin Syringe

Indications for Use *(Describe)*
It is intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes. The safety shield is intended to reduce the risk of sharp injuries.

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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K210712 510(k) Summary

1 Date Prepared

Sep 7th, 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: Verifine Mechanical Safety Insulin Syringe

Classification name: Syringe, Piston

Regulation Number: 21 CFR 880.5860

Device Class: Class II

Product Code: FMF, FMI (hypodermic needle)

4 Identification of Predicate Device

K193273: Insulin Syringe

Classification name: Syringe, Piston

Regulation Number: 21 CFR 880.5860

Device Class: Class II

Product Code: FMF

5 Description of the Device

Verifine Mechanical Safety Insulin Syringe is a sterile device consisting of a calibrated barrel with plunger intended to be used to administer an injection of insulin to a patient subcutaneously.

It includes an attached needle with a safety mechanism, i.e, after the injection, the protective shield will permanently be locked in place by pushing forward till click, providing protection against needle sticks and rendering the device unusable.

It can be used by health care personnel. This is a single-use device.

Gauge	Length	Wall Type
29G	6 mm	Regular Wall Thin Wall
	8 mm	
	10 mm	
	13mm	
30G	6 mm	
	8 mm	
	10 mm	
	13mm	
31G	4 mm	
	6 mm	
	8 mm	
	10 mm	
	13mm	
32G	4 mm	

6 Indication for Use

Characteristics	Subject Device Verifine Mechanical Safety Insulin Syringe K210712	Predicate Device Insulin Syringe K193273

Indication for Use	It is intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes. The safety shield is intended to reduce the risk of sharp injuries.	Insulin Syringe is intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes.
Prescription Only or Over the counter	Prescription Only	Prescription Only

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

The Verifine Mechanical Safety Insulin Syringe is substantially equivalent to the predicate device, the Insulin Syringe (K193273) 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 above 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.

	Subject Device	Predicate Device (K193273)	Comments
Trade Name	Verifine Mechanical Safety Insulin Syringe	Insulin Syringe	
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd	Promisemed Hangzhou Meditech Co., Ltd	
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 for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes. The safety shield is intended to reduce the risk of sharp injuries.	Insulin Syringe is intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes.	Similar The subject device has additional safety shield to prevent sharp injury.
Operating Principle	The insulin is injected to subcutaneous tissue by pushing force generated	The insulin is injected to subcutaneous tissue by pushing force generated	Different The subject device has

	through pushing plunger rod of the insulin syringe. The protective shield will permanently be locked in place by pulling forward till click, providing protection against needle sticks.	through pushing plunger rod of the insulin syringe.	additional safety shield to prevent sharp injury.
Volume	0.3ml,0.5ml,1.0ml	0.3ml,0.5ml,1.0ml	Same
Gauge	32G, 31G, 30G, 29G	32G, 31G, 30G, 29G, 28G	Different The gauge range of subject device is within that of predicate device.
Dead Space	Maximum dead space 0.01ml	Maximum dead space 0.01ml	Same
Wall Type	Regular wall, Thin wall	Regular wall, Thin wall	Same
Needle Length	4mm, 6mm, 8mm,10mm, 13mm	6mm, 8mm,12mm	Different Subject device has wider needle length than predicate device.The specification of 4mm and 13mm meets the requirement of ISO9626, ISO7864 and ISO8537.
Needle tip configuration	3 bevels	3 bevels	Same
Nozzle type	Not applicable	Not applicable	Same
Numbering of scale	At every five units for the 0.3mL and 0.5mL syringes, and at every 5 or 10units for 1.0mL syringe	At every five units for the 0.3mL and 0.5mL syringes, and at every 10units for 1.0mL syringe	Same
Gradations legibility	Legible	Legible	Same
Needle cover color	Red (U-40) and orange (U-100)	Red (U-40) and orange (U-100)	Same
Lubricant	Silicone oil	Silicone oil	Same
Lubricant amount/cm^2	The lubricant is not form pools of fluid on the interior surface of the syringe or outside surfaces of the needle tube	The lubricant is not form pools of fluid on the interior surface of the syringe or outside surfaces of the needle tube	Same
Barrel transparency	Transparent	Transparent	Same
Reuse durability	Single Use	Single Use	Same
Hub/needle bond strength	Bond between hub and needle tube should be no less than	Bond between hub and needle tube should be no less than	Same

	Nominal outside diameter of needle (mm) / Minimum shearing strength ≥0.33 / 22N <0.33 / 11N	Nominal outside diameter of needle (mm) / Minimum shearing strength ≥0.33 / 22N <0.33 / 11N	
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 and Subacute Systemic Toxicity: No systemic toxicity -Hemolysis: No evidence of hemolysis -Pyrogen: Non pyrogenic	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 and Subacute Systemic Toxicity: No systemic toxicity -Hemolysis: No evidence of hemolysis -Pyrogen: Non pyrogenic	Same
Configuration and Materials	Needle: Stainless Steel (SUS304) Barrel: Polypropylene Plunger: Polypropylene Push-bottom: Polypropylene Needle cap: Polyethylene Piston: Polyisoprene rubber Sliding Sleeve, Cover: Polypropylene Plug, Supporting bar: Acrylonitrile Butadiene Styrene	Needle: Stainless Steel (SUS304) Barrel: Polypropylene Plunger: Polypropylene Push-bottom: Polypropylene Needle cap: Polyethylene Piston: Polyisoprene rubber	Same
Label	Device name, indication, instruction for use, precaution, warning, shelf life, manufacturer	Device name, indication, instruction for use, precaution, warning, shelf life, manufacturer	Same
Sterilization method and SAL	EO Sterilization SAL = 10^{-6}	EO Sterilization SAL = 10^{-6}	Same

8 Discussion of differences in technological characteristics

- Considering the skin thickness of different populations, additional length is added for patients to choose from. The additional length does not affect the effectiveness and safety of the device.

- The gauge range of subject device is within that of predicate device. The different gauge range does not impact the effectiveness and safety of the device.
- The operating procedure for insulin injection process is the same as predicate device. The subject device has additional safety shield to protect against sharps injury.

9 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 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 8537:2016, Sterile single-use syringes, with or without needle, for insulin
- 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
- Simulated clinical use testing was conducted as recommended in FDA guidance, Medical Devices with Sharps Injury Prevention Features.

Biocompatibility

In accordance with ISO 10993-1 the device is classified as External communicating device, Blood path, indirect, with prolonged contact duration (> 24h to 30d). It is leverage for the predicate the following testing;

- 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 and pyrogen test
- ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity-Subacute systemic toxicity
- ISO 10993-4:2017, Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood, Hemocompatibility
- USP42-NF37<151> Pyrogen Test
- Particulate matter testing was conducted in accordance with USP <788> Particulate Matter in Injections and met the USP acceptance criteria.

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

10 Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Verifine Mechanical Safety Insulin Syringe is substantially equivalent to the Insulin Syringe with respect to the indications for use, target populations, treatment method, and technological characteristic.