April 22, 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: K210065
Trade/Device Name: Verifine Safety Type Insulin Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: March 23, 2021
Received: March 23, 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 Rumi Young
Acting 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)*
K210065

Device Name
Verifine Safety Type Insulin Pen Needle

Indications for Use *(Describe)*
Verifine Safety Type Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin.

Additionally, after withdrawal of the Verifine Safety Type Insulin Pen Needle from the body, the attached needle safety shield automatically covers the needle to minimize the risk of accidental needlestick.

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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510(k) Summary

1 Date Prepared

April 22nd, 2021

2 Submitter's Information

Submission Sponsor:

Name: Promisemed Hangzhou Meditech Co., Ltd.

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Submission Correspondent:

Name: Vee Care (Asia) Limited

Address: 17F Chung Pont Commercial Building, 300 Hennessy Road, Hong Kong, China

Contact Name: Wei-Shan Hsu

E-mail: ws@vee.com.hk

3 Trade Name, Common Name, Classification

Trade/Product Name: Verifine Safety Type Insulin Pen Needle

Common Name: Insulin Pen Needle

Classification name: Needle, Hypodermic, Single Lumen

Regulation Number: 21 CFR 880.5570

Device Class: Class II

Product Code: FMI

4 Identification of Predicate Device(s)

K161950: Verifine Safety Type Insulin Pen Needle

5 Description of the Device

Verifine Safety Type Insulin Pen Needle is manufactured by Promisemed Hangzhou Meditech Co., Ltd, which is designed for use with a pen injector for the subcutaneous injection of insulin.

The Verifine Safety Type Insulin Pen Needle consists of needle tube, trigger shield, spring, fixer, needle hub, needle container, UV glue and silicone oil. UV glue is used to glue needle tube and needle hub and the silicone oil is used to needle tube lubrication.

The user proceeds with inserting the needle into the skin manually. Verifine Safety Type Insulin Pen Needle is designed to reduce occurrence of accidental needle sticks from patient end of the needle by providing a shield that covers and locks the needle after use. As the user proceeds with inserting the needle into the skin the shield will retract. After the injection is completed and needle is removed from the skin, the shield will automatically extend to cover the needle and lock in place. Once the Safety Type Insulin Pen Needle is in the locked mode, it can no longer be used.

Verifine Safety Type Insulin Pen Needle is sterile with a Sterility Assurance Level (SAL) of 10^{-6}, non-pyrogenic and single-use devices. It is supplied with several models. Different models are distinguished by needle gauge and length.

6 Indications for Use

Verifine Safety Type Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin.

Additionally, after withdrawal of the Verifine Safety Type Insulin Pen Needle from the body, the attached needle safety shield automatically covers the needle to minimize the risk of accidental needlestick.

7 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: Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods

- ISO11608-2: Needle-based injection systems for medical use — Requirements and test methods — Part 2: Needles • ISO 7864: Sterile hypodermic needles for single use — Requirements and test methods
- ISO 23908: Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- Biocompatibility
  a. ISO 10993-1:2009 – Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process
  b. ISO 10993-5:2009 – Biological Evaluation of Medical Devices -- Part 5: Tests for in Vitro Cytotoxicity
  c. ISO 10993-10:2010 – Biological Evaluation of Medical Devices -- Part 10: Tests for Irritation and Skin Sensitization
  d. ISO 10993-11:2006, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity-Acute systemic toxicity and pyrogen test
  f. ASTM F756-13 Standard Practice for Assessment of Hemolytic Properties of Materials

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

The Verifine Safety Type Insulin Pen Needle is substantially equivalent to the predicate device, the Verifine Safety Type Insulin Pen Needle (K161950) in that these devices have identical designs, methods of construction and operation, and indications for use. The differences from the predicate is the sterilization method. 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 (K161950)	Comments
Trade Name	Verifine Safety Type Insulin Pen Needle	Verifine Safety Type Insulin Pen Needle	
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd	Promisemed Hangzhou Meditech Co., Ltd	
Device Class	Class II	Class II	Same

Product Code	FMI	FMI	Same
Regulation number	880.5570	880.5570	Same
Regulation Name	Needle, Hypodermic, Single Lumen	Needle, Hypodermic, Single Lumen	Same
Intended Use/ Indications for Use	The Safety Type Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin. Additionally, after withdrawal of the Safety Type Insulin Pen Needle from the body, the attached needle safety shield automatically covers the needle to minimize the risk of accidental needlestick.	The Safety Type Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin. Additionally, after withdrawal of the Safety Type Insulin Pen Needle from the body, the attached needle safety shield automatically covers the needle to minimize the risk of accidental needlestick.	Same
Operating Principle	As the user proceeds with inserting the needle into the skin the shield will retract. After the injection is completed and needle is removed from the skin, the shield will automatically extend to cover the needle and lock in place. Once the Safety Type Insulin Pen Needle is in the locked mode, it can no longer be used.	As the user proceeds with inserting the needle into the skin the shield will retract. After the injection is completed and needle is removed from the skin, the shield will automatically extend to cover the needle and lock in place. Once the Safety Type Insulin Pen Needle is in the locked mode, it can no longer be used.	Same
Gauge	G29, G30, G31	G29, G30, G31	Same
Needle Length	4mm,5mm,6mm,8mm	4mm,5mm,6mm,8mm	Same
Sharps Injury Prevention Features	Trigger shield	Trigger shield	Same
Configuration and Material	Needle Tube: X5CrNi18-10	Needle Tube: X5CrNi18-10	Same
	Needle Hub: Polyformaldehyde (POM)	Needle Hub: Polyformaldehyde (POM)	Same
	Fixer: Polyformaldehyde (POM)	Fixer: Polyformaldehyde (POM)	Same
	Spring: 0Cr18Mn8Ni5N	Spring: 0Cr18Mn8Ni5N	Same
	Needle container: Polypropylene (PP)	Needle container: Polypropylene (PP)	Same
	Trigger shield: Acrylonitrile Butadiene Styrene (ABS)	Trigger shield: Acrylonitrile Butadiene Styrene (ABS)	Same
Performance	Complied with ISO 7864, ISO 9626, ISO 11608-2 and ISO 23908	Complied with ISO 7864, ISO 9626, ISO 11608-2 and ISO 23908	Same
Sterilization	EO Sterilization	Gamma Sterilization	Different[1] The sterilization validation has

			been performed (Appendix 16A). A 5 years shelf-life has been validated supported by accelerated aging testing using EO sterilized product (Appendix 16B).
	SAL:10^{-6}	SAL:10^{-6}	Same
Shelf Life	5 years	5 years	Same
Single use	Yes	Yes	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: No pyrogenic -Repeated exposure systemic toxicity: No systemic toxicity	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: No pyrogenic	Different[2]

9 Justification for the differences:

1) Different Sterilization

The proposed sterilization method for the subect device is Ethylene Oxide sterilization as opposed to the predicate device which is sterilized by Gamma Irradiation. This difference in sterilization does not raise any additional concerns of safety or effectiveness because the proposed device met the necessary biocompatibility and sterility testing requirements per ISO 10993.

2) Different Biocompatibility

In addition to the Biocompatibility testing of the predicate device, the subject device was tested for Repeated Exposure Systemic Toxicity due to the nature

of the device and the possibility of inadvertant reuse. This additional testing does not raise any additional concerns of safety or effectiveness.

10 Conclusion

Based on the information provided within this 510(k) submission, proposed Verifine Safety Type Insulin Pen Needle is substantially equivalent to the predicate device (K161950) and is as safe, as effective and performs as well as the legally marketed predicate device.