September 19, 2022

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: K220129
Trade/Device Name: Promisemed X-Safety Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: August 24, 2022
Received: August 24, 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) 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)*
K220129

Device Name
Promisemed X-Safety Pen Needle

Indications for Use *(Describe)*
Promisemed X-safety pen needle is intended for use with needle based injector for the injection of drugs.

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.

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510(k) Summary

1 Date Prepared

September 19, 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

3 Trade Name, Common Name, Classification

Trade/Product Name: X-Safety Pen Needle

Common Name: Hypodermic single lumen 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)

K163578: EasyTouch Safety Pen Needle

5 Description of the Device

X-Safety Pen Needle is a single-use, double-ended, sterile needles for needle-based injection systems (NISs) that fulfil the specifications of ISO 11608-1.

This device is constructed as a double-ended, stainless steel needle of various sizes that is with a threaded plastic hub.

The device includes needle shielding safety features (at both patient-end and cartridge-end or at patient-end only) to reduce the risk of needle stick injury and its container can be provided as short or long type.

It is packaged in a sealed sterility barrier, and the needle is lubricated.

This is a single-use device and delivered sterile. Sterilization process is validated according to EN ISO 11135. Sterilization process undergoes routine control.

6 Intended Use

Promisemed X-safety pen needle is intended for use with needle based injector for the injection of drugs.

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

Promisemed X-Safety Pen Needle is substantially equivalent in its technologies and functions to the EasyTouch Safety Pen Needle which cleared under premarket notification number K163578. The following are comparisons between subject device and the predicate device.

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

	Subject Device	Predicate Device (K163578)	Comments
Trade Name	Promisemed X-Safety Pen Needle	EasyTouch Safety Pen Needle	
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd	MHC Medical Products, LLC.	
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	Promisemed X-Safety Pen Needle is intended for use with needle based injector for the injection of drugs.	The EasyTouch™ Safety Pen Needle is intended for use with pen injector devices for the injection of drugs, including insulin and exenatide. Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection.	Same The subject device include needle shielding safety features (at both patient end and cartridge end or at patient end only) to reduce the risk of needle stick injury.
Operating Principle	Serves as a single use pen needle. The device is removed from its packaging and screwed into a pen injector device. The patient then injects the medicine by first setting the dose on the pen, and then inserting the needle into the skin and then pressing the button on the pen. After the injection the needle automatically retracts into a shielded housing, thus preventing an accidental needle stick. For safety features at both patient end and cartridge end: A second shield covers the needle tail when the needle is removed from the injector. Once the sharps injury prevention feature is activated, it locks in place and the product can no longer be used again.	Serves as a single use pen needle. The device is removed from its packaging and screwed into a pen injector device. The patient then injects the medicine by first setting the dose on the pen, and then inserting the needle into the skin and then pressing the button on the pen. After the injection the needle automatically retracts into a shielded housing, thus preventing an accidental needle stick.	Different An additional protective design is introduced in subject device (for safety features at both patient end and cartridge end) which prevent accidental needle sticks at the cartridge end upon removal of the needle from the injector.
Gauge	29G, 30G, 31G, 32G	29G, 30G, 31G	Different Subject device has additional gauge size (32G) than predicate device.
Needle Length	4mm, 5mm, 6mm, 8mm	5mm,6mm, 12.7mm	Different

			Subject device has shorter needle length than predicate device.
Material (Needle, Hub, Hub protector, Safety feature)	Needle Tube: 304 Stainless steel X5CrNi18-10	Needle Tube: 304 Stainless steel needle	Same
	Needle Hub: Polypropylene (PP)	Needle Hub: Polypropylene (PP)	Same
	Container: Polypropylene (PP)	Hub protector: Polypropylene (PP)	Same
	Trigger spring/Posterior spring: Stainless steel	Safety Feature: Stainless steel spring	Same
	Lubricant: Silicon oil	Lubricant: Silicon oil	Same
Performance	Complied with ISO 9626, ISO 7864, ISO11608-1, ISO 11608-2	Complied with ISO 9626, ISO 7864, ISO11608-1, ISO 11608-2	Same
Sterilization	EO Sterilization	EO Sterilization	Same
	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 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 and passed - 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	Same

The Promisemed X-Safety Pen Needle has the same intended use and technological characteristics as the predicate device. 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 subject device has additional safety feature at the cartridge end which has been validated through ISO 23908. The subject device has wider gauge size and

shorter needle length than predicate device. The specification of needle length and gauze size fulfil the requirement of ISO 9626:2016 and ISO 7864:2016. The differences between the subject device and its predicate do not alter the intended use and do not raise new questions of safety and effectiveness.

8 Performance Testing Summary

The bench testing performed verifies that the performance of the subject devices 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

- ISO 10993-1:2018 – Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process
- 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 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity-Subacute systemic toxicity

- ASTM F756-13 Standard Practice for Assessment of Hemolytic Properties of Materials
- USP42-NF37<151> pyrogen test
- USP39 NF34<85> Endotoxin test (LAL)
- 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 ISTA-3A 2008, 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 ASTM F1980-07 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 proposed subject device is substantially equivalent to the predicate device and is as safe, as effective and performs as well as the legally marketed predicate device.