November 24, 2020

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 0000
China

Re: K202682
Trade/Device Name: Promisemed Triple Safety Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: September 22, 2020
Received: October 26, 2020

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,

Rumi Young
Acting Assistant Director Injection Team
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)*
K202682

Device Name
Promisemed Triple Safety Pen Needle

Indications for Use *(Describe)*
Promisemed Triple Safety Pen Needle is intended for use with pen injector devices for subcutaneous injection of insulin.

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."

510(k)Summary K202682

1 Date Prepared

November 20th, 2020

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 Triple Safety 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

510(K) Number: K191853

Product Code: FMI

Regulation Number: 21 CFR 880.5570

Product Name: Dual Safety Pen Needle

5 Description of the Device

Promisemed Triple Safety Pen Needle is designed for use with a pen injector for the subcutaneous injection of insulin. The user proceeds with inserting the needle into the skin manually.

The Promisemed Triple Safety Pen Needle consists of needle tube, trigger shield, posterior trigger, trigger/posterior trigger 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.

Promisemed Triple Safety Pen Needle is the modification of Dual Safety Pen Needle cleared in K91853. The baseline location of trigger shield (patient end shield) is adjusted to allow the needle tube be covered by trigger shield thoroughly before use. This modification prevents accidental needle sticks before inserting the needle into the skin while the needle container is removed. As the user proceeds with inserting the needle into the skin the shield will retract. A click of the trigger shield (patient end shield) indicates the needle has fully penetrated the skin.

In addition to above protective design, Promisemed Triple Safety Pen Needle retains two safety shields lock as the predicate has: the shield will lock in place (i) after use (patient-end): after the injection is completed and needle is removed from the skin, the shield will automatically extend to cover the needle again and lock in place and (ii) upon removal of the needle from the pen (pen connector-end): the posterior trigger (a second shield) covers the pen connector needle when it is removed from the pen. Once the Promisemed Triple Safety Pen Needle is in the locked mode, it can no longer be used.

Promisemed Triple Safety 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.

Gauge	Length	Wall Type

29G	**4,5,6,8 mm**	**Thin wall**
30G	**4,5,6,8 mm**	**Thin wall**
31G	**4,5,6,8 mm**	**Thin wall**

6 Intended Use

Promisemed Triple Safety Pen Needle is intended for use with pen injector devices for subcutaneous injection of insulin.

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

The Promisemed Triple Safety Pen Needle is substantially equivalent to the predicate device, the Dual Safety Pen Needle (K191853) in that these devices have similar designs, methods of construction and operation, and indications for use. The differences from the predicate is the change of assembled position of trigger shield, the performance of which was verified and validated through ISO 7864, ISO23908, and ISO 11608–2 testing (See Section 8). 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 (K191853)	Comments
Trade Name	Promisemed Triple Safety Pen Needle	Dual Safety 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	Promisemed Triple Safety Pen Needle is intended for use with pen injector devices for subcutaneous injection of insulin.	The Dual Safety Pen Needle is intended for use with pen injector devices for subcutaneous injection of insulin. The product has two safety shields which lock in place after use	Different The Subject device has one more protective design compared to predicate device that the needle tube is covered

		(patient-end) and upon removal of the needle from the pen (pen connector-end). The lock shields help reduce the occurrence of needle sticks from both ends of the needle.	thoroughly by trigger shield before use. The difference in the protective mechanism to the predicate did not affect the substantantially equivance on safety and effectiveness of the device
Operating Principle	The needle tube is covered by trigger shield and is not exposed before usage. 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 again and lock in place. A click of the patient end shield indicates the needle has fully penetrated the skin. A second shield covers the pen connector needle when the needle is removed from the pen. Once the Promisemed Triple Safety 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. A click of the patient end shield indicates the needle has fully penetrated the skin. A second shield covers the pen connector needle when the needle is removed from the pen. Once the Dual Safety Pen Needle is in the locked mode, it can no longer be used.	Different The needle tube in the subject device is covered by trigger shield and is not exposed before usage. While the predicate the needle is not covered before usage. However, the difference in the covering of the needle tube does not affect the substatially equivalence on the safety and effectiveness
Gauge	G29, G30, G31	G29, G30, G31	Same
Needle Length	4mm,5mm,6mm,8mm	4mm,5mm,6mm,8mm	Same
Needle wall thickness	Thin Wall	Thin Wall	Same
Lubricant	Silicone Oil	Silicone Oil	Same
Adhesive	UV glue	UV glue	Same
Sharps Injury Prevention Features	The needle tip is covered by trigger shield and is not exposed before use. The patient end of the device has a mechanism that allows the needle to be shielded and locked after use. The non-patient (pen	The patient end of the device has a mechanism that allows the needle to be shielded and locked after use. The non-patient (pen connection) end of the cannula is visible prior to attachment to the pen injector. Following	Similar An additional protective design is introduced in subject device which prevent accidental needle sticks during the interval after the

	connection) end of the cannula is visible prior to attachment to the pen injector. Following removal of the device from the pen injector, the needle is shielded with a mechanism that is designed to reduce the occurrence of accidental needle stick injuries.	removal of the device from the pen injector, the needle is shielded with a mechanism that is designed to reduce the occurrence of accidental needle stick injuries.	needle container is removed and before inserting the needle into the skin.
Trigger force	≤ 0.7N	Not applicable	An additional protective design is introduced in the subject device which prevent accidental needle sticks during the interval after the needle container is removed and before inserting the needle into the skin . Tested in accordance to ISO 7864:2016, Annex D to ensure that the trigger shield will retact during injection and after injection
Method of attachment to the pen injector	(a) Removed the seal from the needle container. (b) Push the needle straight on to the pen injector and screw until it is tight	(a) Removed the seal from the needle container. (b) Push the needle straight on to the pen injector and screw until it is tight	Same
Angle of insertion	90° vertical to the desired injection site	No particular angle	Different Since the needle of subject device is inside the shield before use, the insertion angle of 90° vertical is recommended to make sure the needle inserts to the desired position. The difference did not affect the substiantially equivalence on

			safety and effectiveness.
Configuration and Material			Different The needle tube is not exposed in subject device. While in the predicate it is exposed before usage
	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
	Posterior Trigger: Acrylonitrile Butadiene Styrene (ABS) and Pigment red 122(CAS: 980-26-7)	Posterior Trigger: Acrylonitrile Butadiene Styrene (ABS) and Pigment red 122(CAS: 980-26-7)	Same
	Trigger shield A: Acrylonitrile Butadiene Styrene (ABS) and color additive [Green: Chromium(III) oxide(CAS 1308-38-9); Violet: P.V 23 (CAS 6358-30-1); Orange: Nickel Antimony Titanate Yellow (CAS 8007-18-9); Blue: Pigment Blue 29 (CAS 57455-37-5)]	Trigger shield A: Acrylonitrile Butadiene Styrene (ABS) and color additive [Green: Chromium(III) oxide(CAS 1308-38-9); Violet: P.V 23 (CAS 6358-30-1); Orange: Nickel Antimony Titanate Yellow (CAS 8007-18-9); Blue: Pigment Blue 29 (CAS 57455-37-5)]	Material is the same. The location slot in subject device is moved downward. This change makes the baseline position of trigger shield move upward in finished subject device which allowing the needle tube be covered thoroughly.
	Trigger shield B: Acrylonitrile Butadiene Styrene (ABS)	Trigger shield B: Acrylonitrile Butadiene Styrene (ABS)	Same
Trigger Shield Slot	Lower	Higher	Different The location of the slot in subject device is moved downward. This change allows the trigger shield cover the needle tip

			completely before use. Does not affect the safety and effectivity of the device or the substiantially equivalence to the predicate.
Unit Packaging	Sterile barrier system is consisting of needle container and seal (Medical grade glue dialyzing paper)	Sterile barrier system is consisting of needle container and seal (Medical grade glue dialyzing paper)	Same
Box	Paper board	Paper board	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	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 Systemic Toxicity:No systemic toxicity -Hemolysis: No evidence of hemolysis -Pyrogen: No 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 Systemic Toxicity:No systemic toxicity -Hemolysis: No evidence of hemolysis -Pyrogen: No pyrogenic	Same

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:

- 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

9 Conclusion

Based on the information provided within this 510(k) submission, proposed Promisemed Triple Safety Pen Needle is substantially equivalent to the predicate device (K191853) and does not raise different questions of safety or effectiveness.