December 31, 2020

Promisemed Hangzhou Meditech Co., Ltd.
% Wei-Shan Hsu
Regulatory manager
Vee Care (Asia) Limited
17th Chung Pont Commercial Building, 300 Hennessy Road
Hong Kong, Hong Kong 0000
China

Re: K202681
Trade/Device Name: Promisemed Covered Safety Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: December 7, 2020
Received: December 7, 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
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)*
K202681

Device Name
Promisemed Covered Safety Pen Needle

Indications for Use *(Describe)*
Promisemed Covered Safety Pen Needle is intended for subcutaneous injection of insulin in the treatment of diabetes.

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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K202681 - 510(k) Summary

1 Date Prepared

Dec 30th, 2020

2 Submitter's Information

Name of Sponsor:

Promisemed Hangzhou Meditech Co., Ltd.

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3 Trade Name, Common Name, Classification

Trade/Product Name: Promisemed Covered Safety Pen Needle

Common Name: Needle, Hypodermic, Single Lumen

Classification name: Needle, Hypodermic, Single Lumen

Regulation Number: 21 CFR 880.5570

Device Class: Class II

Product Code: FMI

Review Panel: General Hospital

4 Predicate Device

K161950: Verifine® Safety Type Insulin Pen Needle

Classification name: Needle, Hypodermic, Single Lumen

Regulation Number: 21 CFR 880.5570

Device Class: Class II

Product Code: FMI

5 Description of the Device

Promisemed Covered Safety 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 user proceeds with inserting the needle into the skin manually.

The Promisemed Covered Safety 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.

Promisemed Covered Safety Pen Needle is the modification of Verifine Safety Type Insulin Pen Needle cleared in K161950. The baseline location of trigger 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. 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. Once the Covered Safety Insulin Pen Needle is in the locked mode, it can no longer be used.

Promisemed Covered 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.

The dimension for Promisemed Covered Safety Pen Needle is shown as below.

Model	Needle Outer Diameter	Needle length	Color
CPN-29-4	0.33 mm (29G)	4 mm	Green
CPN-29-5		5 mm	Violet
CPN-29-6		6 mm	Orange

CPN-29-8		8 mm	Blue
CPN-30-4	0.30 mm (30G)	4 mm	Green
CPN-30-5		5 mm	Violet
CPN-30-6		6 mm	Orange
CPN-30-8		8 mm	Blue
CPN-31-4	0.25mm (31G)	4 mm	Green
CPN-31-5		5 mm	Violet
CPN-31-6		6 mm	Orange
CPN-31-8		8 mm	Blue

6 Intended Use

Promisemed Covered Safety Pen Needle is intended for subcutaneous injection of insulin in the treatment of diabetes.

7 Substantial Equivalence Discussion

The Promisemed Covered Safety Pen Needle is substantially equivalent to the predicate device, the Verifine Safety Type Insulin Pen Needle (K161950) in that these devices have similar designs, methods of construction and operation, and indications for use. The differences from the predicate include change of assembled position of trigger shield, and change of sterilization method.

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

	Subject Device	Predicate Device (K161950)	Comments
Trade Name	Promisemed Covered Safety 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	Promisemed Covered Safety Pen Needle is intended for subcutaneous injection of insulin in the treatment of diabetes.	The Safety Type Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin.	Same

		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.	
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. Once the Promisemed Covered 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. 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			Different The needle tube is not exposed in subject device. While in the predicate it is exposed before usage. The modification is verified per ISO 7864:2016, ISO 23908:2011 and ISO 11608-2:2012.
	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) *Location slot is lower	Trigger shield: Acrylonitrile Butadiene Styrene (ABS) *Location slot is higher	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 completely before use. The modification is verified per ISO 7864:2016, ISO 23908:2011and ISO 11608-2:2012.
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 Both are sterilized to SAL 10^{-6} level. The sterilization of subject devie is validated per ISO11135:2014.
	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	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	Same

	-Acute Systemic Toxicity:No systemic toxicity -Hemolysis: No evidence of hemolysis -Pyrogen: No pyrogenic	-Acute Systemic Toxicity:No systemic toxicity -Hemolysis: No evidence of hemolysis -Pyrogen: No pyrogenic	

Discussion:

The differences from the predicate is the change of assembled position of trigger shield, and Sterilization method, the Safety and performance of which were verified and validated through ISO 7864, ISO23908, and ISO 11608–2 testing (See Section 8). The sterilization was validated in accordance with ISO 11135:2014.

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness.

8 Non-Clinical Testing

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 9626:2016 - Needle material
- ISO11608-2:2012 - Needle Dimensions, Flow rate, Bond between hub and needle tube, Needle points, Freedown from defects, Lubrication, Dislocation of measuring point patient end, Functional compatibility with needle-based injected systems, Easy of assemble and disassembly
- ISO 7864:2016 - Pierce Force
- ISO 23908:2011 - Accidental access to a sharp once in safe mode, Safety mechanism activation,Safety overriding and unlocking force after activation
- Biocompatibility

  The subject device was evaluated for the following endpoints per ISO 10993-1:2018, ISO 10993-5: 2009, ISO 10993-10: 2013, ISO 10993-11:2006, ISO 10993-11:2017 and ASTM F756-13 - Cytotoxicity, Sensitization,

Irritation, Acute Systemic Toxicity, Material Mediated Pyrogenicity, Subacute/Subchronic Toxicity, and Hemocompatibility.

- Sterilization

  The subject device complies with ISO 11135:2014, ISO 11737-1:2018, ISO 11737-2:2009 and ISO 10993-7:2008 for EO sterilization.

9 Clinical Testing:

Not Applicable

10 Conclusion

The modifications to the design and sterilization of the subject device met the requirements of the standards. The proposed Promisemed Covered Safety Pen Needle is substantially equivalent to the Safety Type Insulin Pen Needle cleared under K161950 with respect to the indications for use, target populations, treatment method, use enviroment, and technological characteristics.