July 21, 2021
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
China

Re: K210059
Trade/Device Name: Promisemed Insulin Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Received: June 21, 2021

Dear Wei-Shan 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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210059

Device Name
Promisemed Insulin Pen Needle

Indications for Use *(Describe)*
Promisemed Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin. It is sterile and for single use only. It is suitable for all age groups including neonate, infant, children and adult, and can be used by the patient at home or healthcare professionals at medical/health care centers.

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

July 21, 2021

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 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 Common Type Insulin Pen Needle

5 Description of the Device

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

The Promisemed Insulin Pen Needle consists of needle container, needle shield, needle tube, needle hub, 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 Insulin Pen Needle is the modification of the Verifine Common Type Insulin Pen Needle cleared in K161950 in extension of the range of gauge and needle length as well as change in material of needle shield. Promisemed 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

Promisemed Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin. It is sterile and for single use only. It is suitable for all age groups including neonate, infant, children and adult, and can be used by the patient at home or healthcare professionals at medical/health care centers.

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

Promisemed Insulin Pen Needle is substantially equivalent in its technologies and functions to the Verifine Common Type Insulin Pen Needle which cleared under premarket notification number K161950.

Three design changes were made to the subject device, introducion of new gauge specification (34G), new needle length specification(3.5mm and 10mm) and Needle Shield material change. 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 (K161950)	Comments
Trade Name	Promisemed Insulin Pen Needle	Verifine Common 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 Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin. It is sterile and for single use only. It is suitable for all age groups including neonate, infant, children and adult, and can be used by the patient at home or healthcare professionals at medical/health care centers.	The Common Type Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin.	Different The indications for Use is similar except that the subject device specifically identifies intended population, sterile and single use, and for home or healthcare/health care centers
Operating Principle	The user proceeds with inserting the needle into the skin manually. The patient end and the cartridge end of the tube are lubricated using a silicone based lubricant for ease of injection and rubber septum penetration.	The user proceeds with inserting the needle into the skin manually. The patient end and the cartridge end of the tube are lubricated using a silicone based lubricant for ease of injection and rubber septum penetration.	Same
Gauge	29G, 30G, 31G, 32G,33G, 34G	29G, 30G, 31G, 32G,33G	Different New gauge specification (34G) is introduced. This difference does not affect the substantially equivalence on the safety and effectiveness
Needle Length	3.5mm±0.4mm, (4mm, 5mm, 6mm, 8mm, 10mm, 12mm) ±1.2mm	(4mm,5mm,6mm,8mm, 12mm) ±1.2mm	Different Needle length of 3.5 mm and 10mm were newly introduced specifications. This difference does not affect the substantially equivalence on the safety and effectiveness.
Material	Needle Tube: X5CrNi18-10	Needle Tube: X5CrNi18-10	Same
	Needle Hub: Polypropylene (PP)	Needle Hub: Polypropylene (PP)	Same
	Needle container: Polypropylene (PP)	Needle container: Polypropylene (PP)	Same

	Needle shield: Polyethylene (PE)	Needle shield: Polypropylene (PP)	Different Both PE and PP belong are commonly used thermoplastic material. This difference does not affect the substantially equivalence on the safety and effectiveness.
	Joint medium: UV glue	Joint medium: UV glue	Same
	Lubricant: Silicon oil	Lubricant: Silicon oil	Same
	Seal: Dialyzer paper	Seal: Dialyzer paper	Same
Performance	Complied with ISO 7864, ISO 9626, ISO 11608-2	Complied with ISO 7864, ISO 9626, 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 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 Systemic Toxicity:No systemic toxicity -Hemolysis: No evidence of hemolysis -Pyrogen: Non- pyrogenic	Same

Discussion:

The Promisemed Insulin 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 difference in gauge size and material of needle shield does not affect the substantially equivalence on the safety and effectiveness. The Needle length of 3.5mm with tightened tolerance limits (±0.4mm), is within the same needle length range as the predicate 4mm (±1.20 mm), both meet the requirement of ISO 11608-2 to a 95%/95% C/R and substantially equivalent. The subject device has raised no different 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
- 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.
  g. Particulate matter testing was conducted in accordance with USP <788> Particulate Matter in Injections and met the USP acceptance criteria.
  h. Package integrity testing, after environmental conditioning and simulated transportation in accordance with ISTA 3A, was conducted on the final, packaged, and sterile devices. All packaging deemed acceptable for protection of product and sterility maintenance.
  i. Sterile Barrier Packaging Testing performed on the proposed device: Seal strength ASTM F88/F88-15, Dye penetration ASTM F1929-15
  j. 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

9 Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Promisemed Insulin Pen Needle is substancially equivalent to the Verifine Common Type Insulin Pen Needle with respect to the Indications for Use, target populations, treatment method, and technological characteristics.