March 2, 2023

Promisemed Hangzhou Meditech Co., Ltd.
Zearou Yang
Regulatory affairs manager
No. 1388 Cangxing Street, Cangqian Community,
Yuhang District
Hangzhou City, Zhejiang 311121
China

Re: K223453
Trade/Device Name: Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: January 30, 2023
Received: January 30, 2023

Dear Zearou Yang:

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 M. 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)*
K223453

Device Name
Insulin Syringe

Indications for Use *(Describe)*
Insulin Syringe is intended for subcutaneous injection of U-40 and U-100 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1. Date Prepared

Feb. 24, 2023

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: Insulin Syringe

Common Name: Insulin Syringe

Classification name: Piston syringe

Regulation Number: 880.5680

Device Class: Class II

Product Code: FMF

4. Identification of Predicate Device

K110421; Disposable Insulin Syringe

5. Description of the Device

The proposed device Insulin Syringe, a sterile device consisting of a calibrated barrel with plunger, is intended to be used to administer an injection of insulin to a patient subcutaneously. A non-retractable integrated needle is included. The syringe is made of plastic and silicone materials and allowing smooth plunger movement.

This is a single-use device. The device is the same as K193273. The purpose of the submission is to add OTC labeling.

6. Indications for use

Insulin Syringe is intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes.

7. Similarities and Differences of the Proposed Devices to the Predicate Devices

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

Items	Subject Device (K223453)	Predicate Device (K110421)	Comments
Trade Name	Insulin Syringe	Disposable Insulin Syringe	
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd	Wen Zhou Wuzhou Import & Export Co., Ltd.	
Device Class	Class II	Class II	Same
Product Code	FMF	FMF	Same
Regulation number	880.5680	880.5680	Same
Regulation Name	Piston syringe	Piston syringe	Same
Intended Use/ Indications for Use	Insulin Syringe is intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes.	Disposable insulin syringe is a device intended for medical purposes for the manual aspiration of insulin, and for the injection of insulin into parts of the body below the surface skin.	Same
Type of use	Prescription use and over-the-counter use	Over-the-counter use	Different. 1. "Prescription use" of subjective device has been cleared with K193273; 2. "Over-the-counter use" is same with Predicate device; The difference of use type does not impact safety and effectiveness.
Operating Principle	The insulin is injected to subcutaneous tissue by pushing force generated through pushing plunger rod of the insulin syringe.	The insulin is injected to subcutaneous tissue by pushing force generated through pushing plunger rod of the insulin syringe.	Same
Specific drug use	Insulin	Insulin	Same
Length	120mm	120mm	Same
Volume	0.3ml, 0.5ml, 1.0ml	0.3ml, 0.5ml, 1.0ml	Same
Needle length	6mm, 8mm,12mm	5mm, 6mm, 8mm, 12mm	Different. The needle length of proposed device is covered by the predicate device.
Needle gauge	32G, 31G, 30G, 29G, 28G	31G, 30G, 29G, 28G	Different. Compared to the predicate device, the proposed device has an additional 32G model needle. 32G model for insulin syringe

			needle safety and performance has been confirmed by testing. This difference does not raise new questions of safety and effectiveness.
Needle tip configuration	3 bevels	3 bevels	Same
Nozzle type	Not applicable	Not applicable	Same
Numbering of scale	At every five units for the 0.3mL and 0.5mL syringes, and at every 10units for 1.0mL	At every five units for the 0.3mL and 0.5mL syringes, and at every 10units for 1.0mL	Same
Gradations legibility	Legible	Legible	Same
Needle cover dimensions	Length:25mm, Diameter: 6mm	Length:25mm, Diameter: 6mm	Same
Needle cover color	Red (U-40) and orange (U-100)	Red (U-40) and orange (U-100)	Same
Lubricant composition	Aminofuntional siloxane	Aminofuntional siloxane	Same
Lubricant amount/cm^2	The lubricant is not form pools of fluid on the interior surface of the syringe or outside surfaces of the needle tube.	The lubricant is not form pools of fluid on the interior surface of the syringe or outside surfaces of the needle tube.	Same
Barrel transparency	Transparent	Transparent	Same
Needle cover strength	<15N	<15N	Same
Hub/needle bond strength	>22N	>22N	Same
Biocompatibility	No cytotoxicity No irritation reactivity No significant evidence of skin sensitization No significant evidence of systemic toxicity No evidence of Hemolysis No evidence of pyrogens	No cytotoxicity No irritation reactivity No significant evidence of skin sensitization No significant evidence of systemic toxicity No evidence of Hemolysis No evidence of pyrogens	Same
Configuration and Materials	Needle: Stainless Steel (SUS304) Barrel: Polypropylene Plunger: Polypropylene Piston: Polyisoprene rubber Needle cap: Polyethylene Protective end cap (only type 8): Polyethylene	Needle: Stainless Steel (SUS304) Barrel: Polypropylene (PP) Plunger: Polypropylene (PP) Piston: Polyisoprene Rubber Needle cover: Polypropylene (PP) Protective end cap: Polypropylene (PP)	Different. The materials of needle cap and protective end cap are different between the subject device and predicate device. The biocompatibility test of the subject device was conducted to demonstrate that the subject device met the biocompatibility requirements. This difference does not raise any new safety and

			effectiveness questions.
Label	Device name, indication, instruction for use, precaution, warning, shelf life, manufacturer	Device name, indication, instruction for use, precaution, warning, shelf life, manufacturer	Same
Sterilization method and SAL	Sterilized by ethylene oxide gas SAL = 10^{-6}	Sterilized by ethylene oxide gas SAL = 10^{-6}	Same
Sterilization method	EO Sterilization	EO Sterilization	Same
EO and ECH residues testing	Conform ISO 10993-7	Conform ISO 10993-7	Same

8. 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. The data are provided in submission, K193273.

Performance Testing:

The Insulin Syringes have been designed and successfully tested (relying on K193273 submission) to meet the applicable requirements outlined in ISO 8537, such as:

- Needle tube length;
- Diameter of needle tube;
- Bond between hub and needle tube;
- Needle points;
- Freedom from defects;
- Lubrication;
- Fit of plunger stopper in barrel;
- Dead space;
- Freedom from leakage at needle;
- Freedom from leakage past plunger stopper;
- Tolerance on graduated capacity;
- Limits for acidity or alkalinity;
- Limits for extractable metals;
- Fragmentation;
- Penetration force ;
- Particulate contamination;

Biocompatibility testing:

The material of the Insulin Syringes have successfully passed testing as outlined in ISO 10993-1 for devices categorized as External communicating devices, Limited exposure.

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: Test for Irritation and Sensitization

ISO 10993-11: 2006 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity

ISO 10993-4:2017 Biological evaluation of medical devices -Part 4: Selection of tests for interactions with blood.

ASTM F 756-17 Standard Practice for Assessment of Hemolytic Properties of Materials

The United States Pharmacopeia <151> (Pyrogen test), method of limulus amebocyte lysate [LAL].

Sterilization and Shelf-life Testing:

Sterilization of the Insulin Syringes has been validated according to ISO 11135 with half-cycle method.

Testing demonstrated maximum levels of residues of ethylene oxide (≤9mg/d) and ethylene chlorohydrins (≤4mg/d) met with the limits presented in ISO 10993-7. Shelf-life testing supports a shelf life of 5-years after sterilization.

9. Clinical study

No prospective clinical trials were conducted in support of this 510(K).

10. Colorants

The colorant used in the needle cap was listed as below:

Component	Color code	Colorant
Needle cap (U-100)	Orange	PE-M2766
Needle cap (U-40)	Red	PE-M2282

11. 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.