February 26, 2021

Promisemed Hangzhou Meditech Co., Ltd.
% Christy Young
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, Block A, Zhongguan Times Square, Liuxian Avenue,
Xili Town, Nanshan
Shenzhen, Guangdong 518000
China

Re: K193273
Trade/Device Name: Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF

Dear Christy Young:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 5, 2021. Specifically, FDA is updating this SE Letter (E.G., typo in manufacturer name) as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Rumi Young, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, 301-796-6005, Rumi.Young@fda.hhs.gov.

Sincerely,

Rumi Young -S

Digitally signed by Rumi Young -S
Date: 2021.02.26 08:24:54 -05'00'

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

January 5, 2021

Prominsemed Hangzhou Meditech Co., Ltd.
% Christy Young
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, Block A, Zhongguan Times Square, Liuxian Avenue,
Xili Town, Nanshan
Shenzhen, 518000 Cn

Re: K193273
Trade/Device Name: Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: November 14, 2020
Received: December 8, 2020

Dear Christy Young:

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 -S

Digitally signed by Rumi Young -S
Date: 2021.01.05 09:58:10 -05'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K193273

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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

510(k) Number: K193273

1. Contact Details

1.1 Applicant information

Applicant Name	Promisemed Hangzhou Meditech Co., Ltd.
Address	No. 12, Longtan Road, Cangqian Street, Yuhang District, Hangzhou City 311121 Zhejiang, China.
Phone No.	+ 86(0571)88772985
Fax No.	+ 86(0571)88772985
Contact person	Liqing Yang
Date Prepared	October 12, 2020

1.2 Submission Correspondent

卓远天成	Shenzhen Joyantech Consulting Co., Ltd 1713A, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong Province, China.
Phone No.	+86-755-86069197
Contact person	Joyce Yang;
Contact person's e-mail	joyce@cefda.com; cefda@foxmail.com
Website	http://www.cefda.com

2. Device information

Trade name	Insulin Syringe
Common name	Insulin Syringe
Model/Type	Type7, Type8
Classification	Ⅱ
Classification name	Piston syringe
Product code	FMF
Regulation No.	21 CFR 880.5860

3. Legally Marketed Predicate Device

	Primary Predicate Device
Trade Name	Disposable Insulin Syringes
510(k) Number	K162180
Product Code	FMF
Manufacturer	Berpu Medical Technology Co.,Ltd.

4. Device Description

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.

5. Intended Use/Indications for Use

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

6. Substantial Equivalence Comparison

Element of comparison	Proposed Device: Insulin Syringe	Predicate Device: Disposable Insulin Syringe (K162180)	Comment
Product Code	FMF	FMF	Same
Regulation number	21 CFR 880.5860	21 CFR 880.5860	Same
Syringe type	Piston syringe	Piston syringe	Same
Intended use	Insulin Syringe is intended for subcutaneous injection of U-40 and U-100 insulin in the treatment of diabetes.	The disposable insulin syringe is intended for medical purposes for the manual aspiration of U-100 insulin, and for the injection of insulin into parts of the body below the surface skin.	Similar (Note1)
Principle of operation	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	Similar (Note2)
Needle gauge	32G, 31G, 30G, 29G, 28G	31G, 30G, 29G, 28G, 27G	Similar (Note2)
Needle dimensions	0.23mm,0.25mm, 0.30mm, 0.33mm, 0.36mm,	0.25mm, 0.30mm, 0.33mm, 0.36mm, 0.40mm	Similar (Note2)
Needle tip configuration	3 bevels Primary bevel length: (0.84±0.15) mm Primary bevel angle: 10° ± 2°	3 bevels	Same

Element of comparison	Proposed Device: Insulin Syringe	Predicate Device: Disposable Insulin Syringe (K162180)	Comment
	Secondary bevel length: (0.64±0.15) mm Secondary bevel angle: 17° ±2° (The secondary bevel is rotated 35° ±2° to form 2 bevels)		
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)	Orange (U-100)	Similar (Note 1)
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
Reuse durability	Single Use	Single Use	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	Needle: Stainless Steel (SUS304) Barrel: Polypropylene (PP)	Similar (Note3)

Element of comparison	Proposed Device: Insulin Syringe	Predicate Device: Disposable Insulin Syringe (K162180)	Comment
	Plunger: Polypropylene Piston: Polyisoprene rubber Needle cap: Polyethylene Protective end cap(only type 8): Polyethylene	Plunger: Polypropylene (PP) Piston: Polyisoprene Rubber Needle cover: Polypropylene (PP) Protective end cap: Polypropylene (PP)	
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 validation standard	ISO 11135	ISO 11135	Same

Issue:

Note1: The subject device and predicate device have the same indication, that is, for insulin injection. The subject device has another type of syringe for injection of U-40 insulin. The sizes, graduated scale and tolerance on graduated capacity of U-40 insulin syringe are same as the U-100 insulin syringe. The difference between U-40 and U-100 insulin syringe is delivery different insulin concentration. For U-40 insulin syringe, a red needle cap is used for color marking in accordance with ISO 8573. In addition, the tolerance on graduated capacity has been validated per ISO 8573 Annex H. Therefore, this difference does not affect the Substantially Equivalent between the subject device and predicate device.

Note 2: The needle length of proposed device is covered by the predicate device.

The proposed device has extra 32G than the predicate device, and the 32G needle is similar the 31G in dimension. This difference does not affect intended use. In addition, the legally marketed similar device such as Safety Insulin Needle (K181447) has the same needle gauge.

The gauge (32G) for proposed device is different from the predicate device. However, this difference is just in dimension. Different gauge will be selected by physician per patient's condition. This difference does not affect intended use. Differences in needle length and gauge between the predicate and subject device were addressed through ISO 8537:2016 performance testing. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

Note 3: 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. So this difference does not raise any safety and effectiveness problems.

7. Non-clinical studies and tests performed

The Insulin Syringes have been designed and tested to meet the requirements of voluntary standards and FDA guidance documents applicable to the subject and predicate device. The results

of the non-clinical testing supported the conclusion of substantial equivalence.

Performance Testing

The Insulin Syringes have been designed and successfully tested to meet the applicable requirements outlined in ISO 8537:2016 Sterile single-use syringes, with or without needle, for insulin.

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)

The United States Pharmacopeia <788> Particulate matters

Sterilization and Shelf-life Testing

Sterilization of the Insulin Syringes has been validated according to ISO 11135.Testing demonstrated maximum levels of residues of ethylene oxide and ethylene chlorohydrins do not exceed the limits presented in ISO 10993-7. Shelf-life testing supports a shelf life of 5-years after sterilization.

8. Clinical study

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

9. Conclusion

Based on the comparison and analysis above, the proposed devices Insulin Syringes are determined to be Substantially Equivalent (SE) to the predicate devices.