DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 11, 2017

Promisemed Hangzhou Meditech Co., Ltd.
% Field Fu
Consultant
Shenzhen Joyantech Consulting Co., Ltd
No. 55 Shizhou Middle Road, Nanshan District
Shenzhen, GD755 Guangdong
CHINA

Re: K161950
Trade/Device Name: Verifine® Common Type Insulin Pen Needle and Verifine® Safety Type Insulin Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: April 5, 2017
Received: April 10, 2017

Dear Field Fu:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161950

Device Name
Verifine® Common Type Insulin Pen Needle and Verifine® Safety Type Insulin Pen Needle

Indications for Use *(Describe)*
The Common Type Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin.

The Safety Type Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin. 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.

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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K161950

510(k) Summary

1. Contact Details

1.1 Applicant information

Applicant Name	Promisemed Hangzhou Meditech Co.,Ltd.
Address	No.18 Haishu Road Future Sci-Tech Park, Yuhang District, Hangzhou, China
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Fax No.	+86-571-88772985
Contact person	Keshin Hu
Contact person's e-mail	keshin@promisemed.ca
Company e-mail	admin@promisemed.ca
Date Prepared	April 05, 2017
Website	http://www.promisemed.ca/

1.2 Consultant information

Name	Shenzhen Joyantech Consulting Co., Ltd
卓远天成	
Address	Room 1122, International Mayors Communication Centre, NO. 55 Shizhou middle road , Nanshan District, Shenzhen
Phone No.	+86-755-86069197
Contact person	Elly Xu; Field Fu
Contact person's e-mail	elly@cefda.com; info@cefda.com
Website	http://www.cefda.com

2. Device information

Trade name	Verifine® Common Type Insulin Pen Needle; Verifine® Safety Type Insulin Pen Needle
Common name	Insulin Pen Needle
Model	Common Type:IPN-29-12;IPN-30-8;IPN-31-4;IPN-31-5;IPN-31-6; IPN-31-8;IPN-32-4;IPN-32-5; IPN-32-8; IPN-33-4 Safety Type:SPN-29-6;SPN-29-8;SPN-30-4;SPN-30-5;SPN-30-6; SPN-30-8;SPN-31-4;SPN-31-5;SPN-31-6;SPN-31-8
Classification	Ⅱ
Classification name	Needle, Hypodermic, Single Lumen
Product code	FMI
Regulation No.	880.5570

3. Legally Marketed Predicate Device

Trade Name	Insulin Pen Needle
510(k) Number	K133059
Product Code	FMI
Manufacturer	Wenzhou Beipo Science & Technology Co., Ltd

Trade Name	Safe Block Pen Needle
510(k) Number	K151311
Product Code	FMI
Manufacturer	Artsana S.p.A Unit Production N°30, Via Saldarini Catelli 6/10, 22070 Grandate COMO - ITALY

4. Device Description

The proposed product, 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 products have two types, common type and safety type. Both of the two types are sterile with a Sterility Assurance Level (SAL) of 10^{-6}, non-pyrogenic and single-use devices. Each type has several models. Different models are distinguished by needle gauge and length.

The Common Type 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.

The Safety Type Insulin Pen Needle consists of needle tube, needle shield, spring, housing, 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.

The user proceeds with inserting the needle into the skin manually. Safety Type Insulin Pen Needle is designed to reduce occurrence of accidental needle sticks from patient end of the needle by providing a shield that covers and locks the needle after use. 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.

Both the Common Type Insulin Pen Needle and the Safety Type Pen Needle are for OTC use, and they are external communication, blood indirect devices. The contact duration for both subjected devices is within 24h, and they belong to limited contact device according ISO 10993-1.

The dimension for both Common Type Insulin Pen Needle and the Safety Type Pen Needle are shown as below.

Type	Model	Needle OD	Needle available length
Common Type	IPN-29-12	0.33mm	12mm
	IPN-30-8	0.30mm	8mm
	IPN-31-4	0.25mm	4mm
	IPN-31-5	0.25mm	5mm
	IPN-31-6	0.25mm	6mm
	IPN-31-8	0.25mm	8mm
	IPN-32-4	0.23mm	4mm

	IPN-32-5	0.23mm	5mm
	IPN-32-8	0.23mm	8mm
	IPN-33-4	0.20mm	4mm
Safety Type	SPN-29-6	0.33mm	6mm
	SPN-29-8	0.33mm	8mm
	SPN-30-4	0.30mm	4mm
	SPN-30-5	0.30mm	5mm
	SPN-30-6	0.30mm	6mm
	SPN-30-8	0.30mm	8mm
	SPN-31-4	0.25mm	4mm
	SPN-31-5	0.25mm	5mm
	SPN-31-6	0.25mm	6mm
	SPN-31-8	0.25mm	8mm

5. Intended Use/Indication for Use

The Common Type Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin.

The Safety Type Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin.

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.

6. Substantial Equivalence Comparison

6.1 Comparison between Common Type Insulin Pen Needle and Predicate Device(K133059)

Item	**Proposed Device: Common Type Insulin Pen Needle**	**Predicate Device: Insulin Pen Needle (K133059)**	**Comments**
Product Code	FMI	FMI	Same
Intended Use	The Common Type Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin.	The Insulin Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin.	Same
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

Configuration	Needle Tube, Needle shield (Tube Sheath), Needle hub (Hub), Needle container (Hub Sheath), Sealing dialysis paper (Sealed Paper).	Needle Tube, Hub, Tube Sheath, Hub Sheath and Sealed Paper.	Same
Length	4mm, 5mm, 6mm, 8mm, 12mm	4mm, 5mm, 6mm, 8mm, 10mm, 12mm	Similar (* 1)
Needle Gauge	29G/30G/31G/32G/33G	29G/30G/31G/32G	
Tip configuration	Per ISO 11608-2, section 4.5, visually sharp at 2.5X magnification, designed to minimize coring and fragmentation	Per ISO 11608-2, section 4.5, visually sharp at 2.5X magnification, designed to minimize coring and fragmentation	Same
Material	Tube: 304 Stainless Steel	Tube: 304 Stainless Steel	Same
	Needle hub: Polypropylene	Hub: Polypropylene	Same
Performance	Complied with ISO 7864, ISO 9626, and ISO 11608-2	Complied with ISO 7864, ISO 9626, and ISO 11608-2	Same
Sterilization	SAL: 10^{-6}	SAL: 10^{-6}	Same
	Method: EO Sterilized	Method: EO Sterilized	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 pyrogen	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 pyrogen	Same

***1:** The needle tube lengths of the proposed device are covered by the predicate device. Compare to the predicate device, the proposed device has an additional 33G model insulin pen needle. 33G model for Insulin Pen Needle is a widely used in the market and had been approved in FDA (Such as K152410). On the other hand, the bench tests of Needle with 33G demonstrated conformances to ISO 7864, ISO 9626, and ISO 11608-2.

6.2 Comparison between Safety Type Insulin Pen Needle and Predicate Device(K151311)

Item	Proposed Device: Safety Type Insulin Pen Needle	Predicate Device: Insulin Pen Needle (K151311)	Comments
Product Code	FMI	FMI	Same
Intended Use	The Safety Type Insulin Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin. 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.	It is intended for use with pen injector devices for the injection of fluids, including insulin. Additionally the attached safety shield automatically locks in place and reduces the occurrence of accidental sticks from the patient end of the needle. The shield also serves to conceal the needle before and after injection.	Similar(* 2)
Operating Principle	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.	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
Length	4mm, 5mm, 6mm, 8mm(tolerance as per ISO 11608-2)	5mm, 8mm(tolerance as per ISO 11608-2)	Similar (* 3)
Gauge	G29, G30, G31	G31	
Sharps Injury Prevention Features	Safety shield	Safety shield	Same
Configuration and Material	Tube: Stainless Steel	Cannula: Stainless Steel	Same
	Needle Hub: Polypropylene	Needle Hub: Polypropylene	Same
	Spring: Stainless Steel	Spring: Stainless Steel	Same
	Needle container(Primary Container):PP	Primary Container:HDPE	Different (* 4)
	Needle/Safety shield: ABS	Shield:HDPE	

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	SAL: 10-6 Method: Irradiation Sterilized	SAL: 10-6 Method: EO Sterilized	Different (* 5)
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 pyrogen	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 pyrogen	Same

*** 2:** The proposed device is intended to use with pen injector device for subcutaneous injection of insulin. Compare to proposed device, the predicate device is used for the injection of fluids, including insulin. The usage range of proposed device is included in the predicate device.

*** 3:** The length and the gauge is the specification of needle tube that has no relationship with the safety prevention features. The Insulin Pen Needle (K151311) has the tube diameter of 29G and 30G, it also has the tube length of 4mm and 6mm. These models of insulin pen needle are widely used in the market. Moreover, the bench tests of Needles with 29G, 30G and 4mm, 6mm demonstrated conformances to ISO 7864, ISO 9626, ISO 11608-2 and ISO 23908. Therefore the differences do not raise new concerns to establish substantial equivalence to the predicate.

*** 4:** Although the materials of safety shield and needle container between the proposed device and the predicate device are different, the ABS and PP are two kinds of materials that are widely used on medical device. Moreover, the biocompatibility test report of the proposed device demonstrate that subject device is biocompatible and the performance as intended.

*** 5:** Although the sterilization methods between the proposed device and the predicate device are different, but the radiation sterilization effect of the proposed device is proved by the *Microbiological validation report of gamma radiation* and *Radiation sterilization dose audit test report* in VOL_014. The validation report showed that the sterilization effect of the proposed device can achieve a Sterility Assurance Level (SAL) of 10^{-6}, and the radiation dose audit test reports showed that the minimum gamma radiation dose to achieve a 10^{-6} SAL was acceptable according to ISO 11737-2:2012.

7. Non-clinical Testing

All nonclinical testing performed on new devices is to demonstrate the substantial equivalence to the predicate devices. Tests setup and execution are performed in accordance with applicable standards. Results of the testing are demonstrating the compliance to the standards and matching the performance of new devices to the predicate devices.

The following performance data were provided in support of the substantial equivalence determination.

Test		Requirements	Results
Materials		The needle shall be made of tubing materials specified in ISO 9626.	Passed
Dimensions		The needles shall fit the test apparatus specified in item 7.3 of ISO 11608-2.	Passed
Flow rate through the needle		The needles were tested in accordance with Annex A to ISO 11608-2.	Passed
Bond between hub and needle tube		The union of the hub and needle tube shall not break when tested in accordance with Clause 9 of ISO 11608-2.	Passed
Needle points		The needle points shall fulfill the 4.5 of ISO 11608-2.	Passed
Freedom from defects		The needle points shall fulfil the requirements of ISO 7864:1993, 11.3.	Passed
Lubrication		The needle tube should be lubricated at both patient end and the cartridge end. The lubrication shall fulfil the 4.7 of ISO 11608-2.	Passed
Dislocation of measuring point patient end		Dislocation of the cannula point at the patient end shall be in accordance with Table 2 (ISO 11688-2) when tested in accordance with Clause 8 of ISO 11608-2.	Passed
Functional compatibility with needle-based injected systems		Compatibility with any NIS shall be claimed only after testing in accordance with Clause 11 of ISO 11608-2.	Passed
Easy of assemble and disassembly		Attachment of the needle shall be possible without removing the needle from its opened unit packaging. Compliance is checked according to the requirements of Clause 11 of ISO 11608-2.	Passed
Biocompatibility	Cytotoxicity	ISO 10093-5 Biological evaluation of medical devices –Part 5: Tests for in vitro cytotoxicity	Passed
	Sensitization	ISO 10993-10 Biological evaluation of medical devices –Part 10:Tests for irritation	Passed

		and skin sensitization	
	Intracutaneous Reactivity	ISO 10993-10 Biological evaluation of medical devices –Part 10:Tests for irritation and skin sensitization	Passed
	Haemocompatibility	ISO 10993-4 Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood ASTM F765 Standard Practice for Assessment of Hemolytic Properties of Materials	Passed
	System toxicity (acute)	ISO 10993-11:2006/(R)2010, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.	Passed

Simulated Clinical Use Testing

As for Safety Type Insulin Pen Needle, a simulated clinical use testing was conducted to verify the safety feature per FDA guidance document of Medical Devices with Sharps Injury Prevention Features. Based on the guidance, 600 subject devices were chosen in the simulated clinical use testing. There was no needlestick injuries occurred and zero failure of the protective feature in the testing.

8. Clinical Testing

Substantial equivalence does not depend on the clinical test data.

9. Conclusions

Based on device comparison information and non-clinical bench testing, the proposed device is substantially equivalent to legally marketed predicate devices (K133059, K151311).