September 5, 2019

Promisemed Hangzhou Meditech Co., Ltd.
% John Beasley
Senior Consultant
MedTech Review, LLC
257 Garnet Garden Street
Henderson, Nevada 98015

Re: K191853
Trade/Device Name: Dual Safety Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: July 10, 2019
Received: July 10, 2019

Dear John Beasley:

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,

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)*
K191853

Device Name
Dual Safety Pen Needle

Indications for Use *(Describe)*
The Dual Safety Pen Needle is intended for use with pen injector devices for subcutaneous injection of insulin. The product has two safety shields which lock in place after use (patient-end) and upon removal of the needle from the pen (pen connector-end). The lock shields help reduce the occurrence of needle sticks from both ends of the needle.

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

Preparation Date: 09/05/2019

Contact Details	21 CFR 807.92(a)(1)
Applicant Name	Promisemed Hangzhou Meditech Co., Ltd.
Applicant Address	Bldg. 1, No. 12, Longtan Road, Cangqian Street, Yuhang District, Hangzhou City, Zhejiang, 311121, CH
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Correspondent Name	MedTech Review, LLC
Correspondent Address	257 Garnet Garden Street, Henderson, NV, 89015, US
Correspondent Telephone Number	1-612-889-5168
Correspondent Contact	Mr. John Beasley, RAC (US)
Correspondent Contact Email	john@medtechreview.com

Device Name	21 CFR 807.92(a)(2)
Device Trade Name	Dual Safety Pen Needle
Common Name	HYPODERMIC SINGLE LUMEN NEEDLE.
Classification Name	NEEDLE, HYPODERMIC, SINGLE LUMEN
Regulation Number	880.5570
Product Code	FMI

Legally Marketed Predicate Devices		21 CFR 807.92(a)(3)
Predicate [510(k)] #	Predicate Trade Name	Product Code
K161950	Verifine ® Safety Type Insulin Pen Needle	FMI

Device Description Summary

21 CFR 807.92(a)(4)

The device is a pen needle with shields at both the patient end and the pen connector end which are intended to reduce risk of needle stick before and after injections. The patient end mechanism shields the needle before and after an injection, and a second mechanism passively covers the pen connector needle following removal from the pen. A click of the patient end shield indicates the needle has fully penetrated the skin. A second shield covers the pen connector needle when it is removed from the pen.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Dual Safety Pen Needle is intended for use with pen injector devices for subcutaneous injection of insulin. The product has two safety shields which lock in place after use (patient-end) and upon removal of the needle from the pen (pen connector-end). The lock shields help reduce the occurrence of needle sticks from both ends of the needle.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Promisemed adds an additional safety shield to the predicate device such that the subject device's two safety shields lock in place (i) after use (patient-end) and (ii) upon removal of the needle from the pen (pen connector-end). The lock shields help reduce the occurrence of needle sticks from both ends of the needle. This additional protection does not constitute a new intended use. However, the 'Indications For Use' has been revised to reflect the additional safety shield. Both safety pen needle products (the predicate device and the subject device) help protect against accidental needle sticks.

Technological Comparison

21 CFR 807.92(a)(6)

For both the subject and predicate devices, the non-patient (pen connector) ends of the cannula are visible prior to attachment to the pen injector. However, the predicate device is modified such that following removal of the subject device from the pen injector, its needle is shielded with a mechanism designed to reduce the occurrence of accidental needle stick injuries.

Item	**Subject Device K191853**	**Predicate Device K161950**	**Similarities/Differences**
Product Code	FMI	FMI	No difference in FDA product code.
Intended Use	The Dual Safety Pen Needle is intended for use with pen injector devices for subcutaneous injection of insulin. The product has two safety shields which lock in place after use (patient-end) and upon removal of the needle from the pen (pen connector-end). The lock shields help reduce the occurrence of needle sticks from both ends of the needle.	The Safety Type Insulin Pen Needle is intended for use with pen injector devices 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.	The safety pen needle products (subject device and predicate device) help protect against accidental needle sticks and are substantially equivalent in their intended use.
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. A click of the patient end shield indicates the needle has fully penetrated the skin. A second shield covers the pen connector needle when the needle is removed from the pen. Once the Dual 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. This product features an audible cue (a click) when the injection is complete. Once the Safety Type Insulin Pen Needle is in the locked mode, it can no longer be used.	The safety pen needle products (subject device and predicate device) use the same operating principles: the use of lock shields that help reduce the occurrence of needle sticks.
Length	4 $\pm$ 0.5 mm 5 $\pm$ 0.5 mm 6 $\pm$ 0.5 mm 8 $\pm$ 1.2 mm	4 $\pm$ 0.5 mm 5 $\pm$ 0.5 mm 6 $\pm$ 0.5 mm 8 $\pm$ 1.2 mm	The needle tube lengths of the subject device are the same as the predicate device.

Item	Subject Device K191853	Predicate Device K161950	Similarities/Differences
Gauge	29G*6mm 29G*8mm 30G*4mm 30G*5mm 30G*6mm 30G*8mm 31G*4mm 31G*5mm 31G*6mm 31G*8mm	29G*6mm 29G*8mm 30G*4mm 30G*5mm 30G*6mm 30G*8mm 31G*4mm 31G*5mm 31G*6mm 31G*8mm	The available needle lengths per gauge of the subject device are the same as in the predicate device.
Sharps Injury Prevention Features	The patient end of the device has a mechanism that allows the needle to be shielded and locked after use. The non-patient (pen connection) end of the cannula is visible prior to attachment to the pen injector. Following removal of the device from the pen injector, the needle is shielded with a mechanism that is designed to reduce the occurrence of accidental needle stick injuries.	The patient end of the device has a mechanism that allows the needle to be shielded and locked after use.	The sharps injury prevention features of the subject device includes both ends of the needle as compared to only the patient end of the needle in the predicate device.
Device Materials	• Fixer, inside fixer: POM • Hub: POM • Needle hub: X5CrNi18-10 • Springs: 0Cr18Mn8Ni5N • Shield: AB • Container: PP	• Fixer: POM • Hub: POM • Needle tube: X5CrNi18-10 • Spring: 0Cr18Mn8Ni5N • Shield: ABS • Container: PP	The subject device contains an additional posterior trigger spring in comparison to the predicate device. Device materials and both the nature of body contact and the duration of body with the patient/user are the same.
Performance	Complies with • ISO 7864, • ISO 9626, • ISO 11608-2, and • SO 23908	Complies with • ISO 7864, • ISO 9626, • ISO 11608-2, and • ISO 23908	The performance characteristics of the subject device are the same as the predicate device.
Force to Activate Sharps Injury Prevention Feature	Complies with ISO 23908. The force to activate the sharps injury prevention feature is 1N to 5N for both ends of the Dual Safety Pen Needle.	Complies with ISO 23908. The force to activate the sharps injury prevention feature is 1N to 5N for the Safety Type Insulin Pen Needle.	The forces for activate the patient-end sharps injury prevention feature of the subject device are the same as the predicate device. The predicate device does not have a pen-end sharps prevention feature.

Item	Subject Device K191853	Predicate Device K161950	Similarities/Differences
Force to Override Sharps Injury Prevention Feature	Complies with ISO 23908. The force required to override the sharps injury prevention feature greater than 20N for both ends of the Dual Safety Pen Needle.	Complies with ISO 23908. The force required to override the sharps injury prevention feature is greater than 20N for the Safety Type Insulin Pen Needle.	The forces for overriding the patient-end sharps injury prevention feature of the subject device are the same as the predicate device. The predicate device does not have a pen-end sharps prevention feature.
Sterilization	SAL: 10^{-6} Ethylene Oxide Sterilization	SAL: 10^{-6} Gamma Radiation Sterilization	The sterilization methods of the subject and predicate devices are different; however, both are traditional methods of processing medical devices so as to provide sterility assurance levels of 10^{-6}.
Shelf Life	5 years	5 years	Device stability and expiry date of the subject device are the same as the predicate device.
Single Use	Yes	Yes	The safety pen needle products (subject device and predicate device) are single use devices.
Biocompatibility	Complies with ISO 10993 Series Standards for • Cytotoxicity • Skin Irritation • Skin Sensitization • Acute Systemic Toxicity • Hemolysis • Non pyrogenic (material mediated pyrogenicity)	Complies with ISO 10993 Series Standards for • Cytotoxicity • Skin Irritation • Skin Sensitization • Acute Systemic Toxicity • Hemolysis • Non pyrogenic (material mediated pyrogenicity)	The biological safety of the subject device is identical to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-Clinical Summary:

Product functionality: After sterilization, the device meets criteria specified in ISO 11608-2.

Shelf life: Sterile devices meet criteria specified in ISO 11608-2 after accelerated aging. The product is labeled with an expiry date of 5 years.

Biocompatibility: Device meets cytotoxicity requirements of ISO 10093-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Biocompatibility: Device meets sensitization requirements of ISO 10993-10 Biological evaluation of medical devices - Part 10:Tests for irritation and skin sensitization.

Biocompatibility: Device meets intracutaneous reactivity requirements of ISO 10993-10 Biological evaluation of medical devices - Part 10:Tests for irritation and skin sensitization.

Biocompatibility: Device meets hemocompatibility requirements of *both* ISO 10993-4 Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood *and* ASTM F756 Standard Practice for Assessment of Hemolytic Properties of Materials

Biocompatibility: Device meets system toxicity requirements of ISO 10993-11:2006/(R)2010, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

Sharps injury protection: Device meets safety mechanism activation requirements as per ISO 23908,internal protocol and test results

Sharps injury protection: Device meets safety overriding/unlocking force after activation requirements as per ISO 23908, internal protocol and test results

Clinical Simulated Use testing: The testing evaluated whether the posterior safety protective mechanism of the Dual Safety Pen Needle is effective. A total of 8 participants were selected to evaluate the subject device, and included endocrine doctors and nurses who provide training to patients in the use of pen needles for insulin injection. A total of 500 samples were tested and the evaluations resulted in zero failures of each of the two protection features of the Dual Safety Pen Needle.

Sterilization: A Sterility Assurance Level (SAL) of 10^{-6} has been validated in accordance with the requirements of ISO 11135:2014 for Ethylene Oxide.

LAL Pyrogen Testing: Device meets endotoxin requirements of USP39_NF34<85> Bacterial Endotoxins Test.

Packaging: Shipping package meets requirements of ISTA 3A. Unit package functionality meets acceptance criteria specified in ASTM F1929-98 (2004) for dye penetration and peel strength after EO sterilization. The unit package also provides a seal having a microbial barrier that meets log reduction value (LRV) requirements of ASTM F1608-16.

Conclusion:

Based on device comparison information and functional performance bench testing, the proposed device is substantially equivalent to the legally marketed predicate device (K161950).