



December 10, 2025

Promised Hangzhou Meditech Co., Ltd.
Zearou Yang
Regulatory Affairs Manager
No. 1388 Cangxing St.,
Cangqian Community, Yuhang District
Hangzhou City, 311121
China

Re: K250192

Trade/Device Name: Verisafe Safety Retractable Insulin Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, MEG
Dated: November 17, 2025
Received: November 17, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shruti N. Mistry -S

Shruti Mistry

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

Indications for Use

510(k) Number (if known)

K250192

Device Name

Verisafe Safety Retractable Insulin Syringes

Indications for Use (Describe)

Verisafe Safety Retractable Insulin Syringes are intended for aspiration and subcutaneous injection of insulin. After injection, the needle can be retracted directly from the patient's skin into the syringe barrel to avoid exposure to a contaminated needle, thereby minimizing accidental needle stick injuries.

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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K250192 510(k) Summary

Date prepared: 2025-12-10

1. Manufacturer [21 CFR 807.92 (a) (1)]	
Name	Promisemed Hangzhou Meditech Co., Ltd.
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2. Device [21 CFR 807.92 (a) (2)]	
Name	Verisafe Safety Retractable Insulin Syringes
Common Name	Safety Retractable Insulin Syringes
Classification Name	Piston Syringe
Regulation Number	21 CFR 880.5860
Class	Class II
Product Code	FMF, MEG
3. Legally Marketed Predicate Device [21 CFR 807.92 (a) (3)]	
Predicate Name	VeriSafe Safety sterile syringes
510(k) Number	K231792
Product Code	FMF, MEG
Reference Devices	No reference devices were used in this submission.
4. Device Description [21 CFR 807.92 (a) (4)]	
<p>Safety Retractable Insulin Syringes is a sterile device consisting of a calibrated barrel, plunger, piston, push button, retraction cylinder, sealing ring, spring and a needle. It is made of plastic, stainless steel and silicone materials. Type 5 is a syringe with a fixed needle.</p> <p>The needle cap color is used to indicate insulin concentration that red for U40 and orange for U100.</p> <p>Safety Retractable Insulin Syringes is using plunger to fill syringe as well as discharge the fluid. After use, by continuing to press the push-button down to depress the plunger all of the way within the barrel, the safety mechanism will be triggered, then the needle tube, needle hub and retraction cylinder will be retracted into the barrel completely under the force of the spring to minimize the risk of accidental sharps injury.</p> <p>Product is delivered sterile. Sterilization process is validated according to EN ISO 11135.</p> <p>This is a single-use device. Safety Sterile Syringes is intended to be used in Professional Healthcare Facility,</p>	

Home Environment and Transport (Ambulatory) Environment.

5. Indication for use [21 CFR 807.92 (a) (5)]

Verisafe Safety Retractable Insulin Syringes are intended for aspiration and subcutaneous injection of insulin. After injection, the needle can be retracted directly from the patient's skin into the syringe barrel to avoid exposure to a contaminated needle, thereby minimizing accidental needle stick injuries.

6. Indications for Use Comparison [21 CFR 807.92 (a) (5)]

Type 5 is added which its indication is only for insulin and is not affected the safety and effectiveness of the subjective device.

7. Comparison of Technological Characteristic [21 CFR 807.92 (a) (6)]

The subject device has the same technological characteristics as the predicate device. The similarities above between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. And there are no new or different questions of effectiveness and safety when compared to the predicate device. We concluded the subject device is substantially equivalent to the identified predicate device.

At a high level, the subject and predicate devices are based on the following same technological elements:

Item of description	Predicate device (K231792)	Subject device (K250192)	Comments on Similarities/Differences	Safety/Effectiveness Statement
Common name	VeriSafe Safety sterile syringes	Safety Retractable Insulin Syringe	N/A	No new concerns. The common name was to be distinguished for difference indication.
Classification name	Piston Syringe (21 CFR 880.5860)	No change	N/A	No new concerns. The classification name remains consistent.
Device class	Class II	No change	N/A	No new concerns. The device remains in Class II, indicating no change in risk level.
Product Code	FMF, MEG	No change	N/A	No new concerns. The product code remains the same, reflecting no change in device functionality.
General description	Safety Sterile Syringes is a sterile device consisting of a calibrated barrel, plunger, piston, push button, retraction cylinder, sealing ring, spring and a needle. It is made of plastic, stainless steel and silicone materials. Safety Sterile Syringes have two types: Type F and type D. Type F is a syringe with a fixed needle. Type D is a syringe with a detachable needle. The detachable needle is secured by rotating it through the front needle hub into the back needle hub located on the syringe. Safety Sterile Syringes is using plunger to fill syringe as well as discharge the fluid. After use, by continuing to press the push-button down to depress the plunger all of the way within the barrel, the safety mechanism will be triggered, then the needle tube, needle hub and retraction cylinder will be retracted into the barrel completely under the force of the	Safety Sterile Syringes is a sterile device consisting of a calibrated barrel, plunger, piston, push button, retraction cylinder, sealing ring, spring and a needle. It is made of plastic, stainless steel and silicone materials. Type 5 is a syringe with a fixed needle. The needle cap color is used to indicate insulin concentration that red for U40 and orange for U100. Safety Sterile Syringes is using plunger to fill syringe as well as discharge the fluid. After use, by continuing to press the push-button down to depress the plunger all of the way within the barrel, the safety mechanism will be triggered, then the needle tube, needle hub and retraction cylinder will be retracted into the barrel completely under the force of the	Type 5 is added and needle cap color for insulin concentration was added in accordance with ISO 8537:2016.	No new concerns. Type 5 is added which its indication is only for insulin and needle cap color for insulin concentration was added in accordance with ISO 8537:2016.

	<p>spring to minimize the risk of accidental sharps injury. Product is delivered sterile. Sterilization process is validated according to EN ISO 11135. This is a single-use device. Safety Sterile Syringes is intended to be used in professional healthcare facility/hospital and transport environment.</p>	<p>Product is delivered sterile. Sterilization process is validated according to EN ISO 11135. This is a single-use device. Safety Sterile Syringes is intended to be used in professional healthcare facility/hospital and transport environment.</p>		
Principle of operation	<p>Safety Sterile Syringes is using plunger to fill syringe as well as discharge the fluid. After use, by continuing to press the push-button down to depress the plunger all of the way within the barrel, the safety mechanism will be triggered, then the needle tube, needle hub and retraction cylinder will be retracted into the barrel completely under the force of the spring to minimize the risk of accidental sharps injury.</p>	No change	N/A	No new concerns. The principles of operation remain unchanged.
Indication of use	<p>It is intended to inject fluids into the body or withdraw blood for medical purposes. After injection, the needle tube will be retracted into the barrel when the safety features are manually activated to minimize the risk of accidental sharps injury.</p>	<p>Verisafe Safety Retractable Insulin Syringes are intended for aspiration and subcutaneous injection of insulin. After injection, the needle can be retracted directly from the patient's skin into the syringe barrel to avoid exposure to a contaminated needle, thereby minimizing accidental needle stick injuries.</p>	<p>The indication is changed only for insulin.</p>	No new concerns. Type 5 is added which its indication is only for insulin. It has narrowed the indication scope compared to the legally marketed predicate device and does not affect the safety and effectiveness of the subject device.
Type	Type D Type F	Type 5	<p>Type 5 is added which its indication is only for insulin.</p>	No new concerns. Type 5 is added. This does not introduce new risks as the fundamental technology and operation remain the same.
Syringe volume	1ml, 2ml, 3ml, 5ml, 10ml	0.5ml, 1.0ml	<p>Volume is only 0.5ml and 1.0ml.</p>	No new concerns. The narrower volume scope does not introduce new risks as the fundamental technology and operation remain the same.
Needle size	18G, 20G, 22G, 23G, 25G, 27G, 28G, 29G, 30G, 31G, 32G	28G, 29G, 30G, 31G, 32G	<p>Needle gauge is reduced to 28G, 29G, 30G, 31G, 32G.</p>	No new concerns. The narrower gauge scope does not introduce new risks as the fundamental technology and operation remain the same.
Needle length	6mm, 8mm, 12mm, 25mm, 38mm	5mm, 6mm, 8mm, 12mm	<p>Needle length is reduced to 5mm, 6mm, 8mm, 12mm.</p>	No new concerns. The narrower needle length scope does not introduce new risks as the fundamental technology and operation remain the same.
Schematic diagram	Type D, Type F: Remain no change	Type 5: No change	N/A	No new concerns. The change to type

				name and a narrower type does not introduce new risks as the fundamental technology and operation remain the same.
Material	Type D, Type F: Remain no change	Type 5: Needle cap is PE;	Needle cap material is changed from PP to PE;	No new concerns. The change to needle cap has been confirmed to biocompatibility evaluation and doesn't introduce new risk.
Performance requirements	Type D, Type F: Complied with ISO 9626, ISO 7864 and ISO 23908.	Type 5: Complied with ISO 9626, ISO 7864, ISO 8537 and ISO 23908.	Type 5 is intended used for insulin injection.	No new concerns. Performance requirements of type 5 are in accordance with ISO 9626, ISO 7864, ISO 8537 and ISO 23908 ensuring consistent functionality.
Sterilization method	EO Sterilization	EO Sterilization	N/A	No new concerns. The change of type 5 is used the same sterilization method.
Sterility	SAL of 10 ⁻⁶	SAL of 10 ⁻⁶	N/A	No new concerns. The change of type 5 is required the same SAL.
Shelf-life	3 years	3 years	N/A	No new concerns. The change of type 5 is required the same shelf-life.
Single use	Single use	Single use	N/A	No new concerns. The change of type 5 is required of single use.
Biocompatibility	Complied with ISO10993 series standards, and the following tests are performed <ul style="list-style-type: none"> - 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 - USP <788> Particulate matter 	Complied with ISO10993 series standards, and the following tests are performed: <ul style="list-style-type: none"> - 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 - USP <788> Particulate matter; - Subchronic test: No evidence of toxicity; 	Subchronic test was added that no toxicity.	The subchronic testing is added of type 5 that consideration of insulin injection of accumulated using. The testing result is indicated that no toxicity.
Labeling	Type D, Type F: Remain no change	Type 5: Marking of insulin concentration on barrel, unit packaging, user packaging and IFU were updated in accordance with ISO 8537:2016.	Marking of insulin concentration on barrel, unit packaging, user packaging and IFU were updated in accordance with ISO 8537:2016.	No new concerns. Labeling updates meet ISO 8537:2016 and enhance the device's safety and usability.

8. Nonclinical test [21 CFR 807.92 (b) (1)]

To support substantial equivalence to the predicate device, Promisemed Hangzhou Meditech Co., Ltd. completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met.

Verification and Validation Activities - Design Changes:

- ◆ Performance requirements: full performance testing was conducted using the worst-case representative model, including freedom from defects, cleanliness, tube dimensions, stiffness, resistance to corrosion, lubricant, needle point, fragment, patency, leakage, dead space, color code, package, safety mechanism, chemical and biological in accordance with ISO 9626, ISO 7864, ISO 8537 and ISO 23908.
- ◆ Material of needle cap (PE): Biocompatibility of type 5 needle cap (PE) has been confirmed that the material has been used in legally marketed device (K193273, manufactured by PROMISEMED) in the same contact method (intact skin) and duration (limited exposure-A) according to ISO 10993-1:2018.

All verification and validation tests passed without deviations, confirming that the subject device meet the necessary design specifications and regulatory requirements. The tests demonstrated that the product modifications did not introduce any new risks related to safety or effectiveness when compared to the predicate device.

9. Clinical test [21 CFR 807.92 (b) (2)]

No clinical testing is included in this submission.

10. Conclusion [21 CFR 807.92 (b) (3)]

Based on the information provided within this 510(k) submission, the 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.