January 10, 2025

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

Re: K243806
Trade/Device Name: Safety Winged Blood Collection Sets
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI, FPA
Dated: December 6, 2024
Received: December 11, 2024

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,

David Wolloscheck, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243806

Device Name
Safety Winged Blood Collection Sets

Indications for Use *(Describe)*
The safety winged blood collection set is single-use, sterile, winged venipuncture needle bonded to a flexible tubing with or without a luer adapter and/or tube holder. The device is used for blood collection and/or the short-term infusion of intravenous fluids (up to 2 hours under direct clinical supervision). The blood-collection needle is designed to be covered with a safety mechanism, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.

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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Promisemed Hangzhou Meditech Co., Ltd.
No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, P. R. China.

K243806-510(k) Summary

Date prepared: 2025-01-09

1. Manufacturer *[21 CFR 807.92 (a) (1)]*	
Name	Promisemed Hangzhou Meditech Co., Ltd.
Address	No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, P.R.China.
Contact Person	Zearou Yang
Phone	+86 571 88772985
Fax	+86 571 88772985
Email	zearou.yang@promisemed.ca
2. Device *[21 CFR 807.92 (a) (2)]*	
Name	Safety Winged Blood Collection Sets
Common Name	Safety Blood Collection Device for Single Use
Classification Name	NEEDLE, HYPODERMIC, SINGLE LUMEN
Regulation Number	21 CFR 880.5570
Class	Class II
Product Code	FMI, FPA
3. Legally Marketed Predicate Device *[21 CFR 807.92 (a) (3)]*	
Predicate Name	Safety Winged Blood Collection Sets
510(k) Number	K211293
Product Code	FMI, FPA
Reference Devices	No reference devices were used in this submission.
4. Device Description *[21 CFR 807.92 (a) (4)]*	
The Promisemed Safety Blood Collection sets are single-use, sterile, venipuncture needles used for blood collection or short-term infusion of intravenous fluids (up to 2 hours under direct clinical supervision). The blood-collection needle is designed to be covered with a safety mechanism, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.	
5. Indication for use *[21 CFR 807.92 (a) (5)]*	
The safety winged blood collection set is single-use, sterile, winged venipuncture needle bonded to a flexible tubing with or without a luer adapter and/or tube holder. The device is used for blood collection and/or the short-term infusion of intravenous fluids (up to 2 hours under direct clinical supervision). The blood-collection needle is designed to be covered with a safety mechanism, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.	
6. Indications for Use Comparison *[21 CFR 807.92 (a) (5)]*	

The indication of subject device is same as the predicate 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 no question is raised regarding effectiveness and safety. 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	Cleared device (K211293)	Modified device	Comments on Similarities/ Differences	Safety/Effectiveness Statement
Common name	Safety Blood Collection Device for Single Use	No change	N/A	No new concerns. Common name is same.
Classification name	NEEDLE, HYPODERMIC, SINGLE LUMEN (21 CFR 880.5570)	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	FMI, FPA	No change	N/A	No new concerns. The product code remains the same, reflecting no change in device functionality.
General description	The Promisemed Safety Blood Collection sets are single-use, sterile, venipuncture needles used for blood collection or short-term infusion of intravenous fluids (up to 2 hours under direct clinical supervision). The blood-collection needle is designed to be covered with a safety mechanism, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.	No change	N/A	No new concerns. The change to add a new model (RBC) does not introduce new risks as the fundamental technology and operation remain the same.
Principle of operation	When the Safety winged blood collection set is used for venous blood collection. The principle is that the device is connected with the vacuum blood collection tube (met with EN 14820), the negative pressure generated by the vacuum blood collection tube draws human blood out, and the blood enters the vacuum blood collection tube, and the needle is pulled out to complete the blood collection.	No change	N/A	No new concerns. The principles of operation remain unchanged, ensuring consistent performance.

	When the Safety winged blood collection set is used for short-term infusion. The principle is that the device is connected with IV set through by Luer connector, and medicinal solution enters the human body through the infusion set (met with ISO 8536-4) under the action of gravity or thrust, and the needle is pulled out to complete the injection.			
Indication of use	The safety winged blood collection set is single-use, sterile, winged venipuncture needle bonded to a flexible tubing with or without a luer adaper and/or tube holder. The device is used for blood collection and/or the short-term infusion of intravenous fluids (up to 2 hours under direct clinical supervision). The blood-collection needle is designed to be covered with a safety mechanism, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.	No change	N/A .	No new concerns. The change to add a new model (RBC) does not introduce new indications as the fundamental technology and operation remain the same.
Model	SBC	RBC is added.	Model RBC is added.	No new concerns. The change to add a new model (RBC) does not introduce new indications as the fundamental technology and operation remain the same.
Type	SBC: Type H, A, S Remain no change	RBC: Type H, A, S	Model RBC is added.	No new concerns. The addition of a new model (RBC) does not affected the safety and effectiveness which type is remain same.
Needle size	21G, 23G, 25G	RBC: 21G, 22G, 23G, 24G, 25G	22G, 24G is added.	No new concerns. The broader needle gauge expands options without altering the device's safety or effectiveness.
Needle length	10cm, 19cm, 30cm	No change	N/A	No new concerns. The addition of a new model (RBC) does not affected the safety and effectiveness which needle length is remain same.

Color	SBC: Remain no change	RBC: Gauge / Color 21G – Deep green 22G – Black 23G – Deep blue 24G – Medium purple 25G – Orange	Color of 22G, 24G is added.	No new concerns. The broader needle gauge expands options without altering the device's safety or effectiveness. The color system is in accordance with ISO 6009 requirement.
Tubing length	Remain no change	No change.	N/A	No new concerns. The addition of a new model (RBC) does not affected the safety and effectiveness which type is remain same.
Schematic diagram	SBC: Remain no change	RBC is same with SBC exempt the safety protective mechanism.	The configuration is similar that operation method is same.	No new concerns. The addition of a new model (RBC) does not introduce new risks as the fundamental technology and operation remain the same.
Material	Remain no change. Safety protective mechanism is ABS.	RBC: Safety protective mechanism is PP. Others component are same with SBC exempt the safety protective mechanism.	Safety protective mechanism material is difference which it is only contact intact skin as limited exposure (A).	No new concerns. Material of RBC is PP which it is only contact intact skin as limited exposure (A), does not introduce new risks about biocompatibility safety.
Sterility	SAL of 10^{-6} Remain no change	No change.	N/A	No new concerns. The addition of a new model (RBC) does not introduce new risks as the fundamental technology and operation remain the same.
Shelf life	3 years Remain no change	No change.	N/A	No new concerns. The addition of a new model (RBC) does not introduce new risks as the shelf life remain the same.

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:

- Model RBC: Visual inspections were conducted on unit packaging to ensure RBC labeling is correct.
- Needle size, color and schematic diagram: Full performance was tested, including appearance, dimension, safety mechanism, labeling, etc. and found to comply with drawing requirements.

Applicable standards:

- ISO 6009:2016, Hypodermic needles for single use - Colour coding for identification.
- ISO 8536-4: 2019, Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed.
- ISO 9626:2016, Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods.
- ISO 23908:2011, Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.

◆ Material: the material of the subject device (RBC) safety protective mechanism has been changed to PP from polypropylene (ABS), which only contacts the intact skin as limited exposure (A). Material PP has been used in the PROMISEMED's own legally marketed device (K230715) wing hub. K230715's biocompatibility testing (Externally communicating device, in contact with circulating blood with prolonged exposure B) was performed in accordance with ISO 10993-1 to support this change and does not raise new or different questions of safety and effectiveness, e.g. In vitro cytotoxicity testing in accordance with ISO 10993-5:2009.

All verification and validation tests passed without deviations, confirming that the subjective 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 test 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.