May 1, 2026

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

RE: K261045
Trade/Device Name: Verifine Safety Lancets
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: April 2, 2026
Received: April 2, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.05.01 15:39:46 -04'00'

Colin Kejing Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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)*
K261045

Device Name
Verifine Safety Lancet

Indications for Use *(Describe)*
The VeriFine Safety Lancet is intended for capillary blood sampling.

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.

K261045-510(k) Summary

Date prepared: 2026-05-01

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, China.
Contact Person	Zearou Yang
Phone	86 571 88772985
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2. Device *[21 CFR 807.92 (a) (2)]*	
Name	VeriFine Safety Lancet
Common Name	Blood Lancet
Classification Name	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature
Regulation Number	21 CFR 878.4850
Class	Class II
Product Code	FMK
3. Legally Marketed Predicate Device *[21 CFR 807.92 (a) (3)]*	
Predicate Name	Verifine Safety Lancets
510(k) Number	K221368
Product Code	FMK
Reference Devices	No reference devices were used in this submission.

4. Device Description *[21 CFR 807.92 (a) (4)]*

The VeriFine Safety Lancet is a sterile, single use, spring-loaded devices designed for capillary blood sampling. The device is available in two configurations: needle type and blade type. The lancets feature precision-sharpened needles designed to provide maximum comfort and optimal blood flow during use.

The safety lancets are designed to make capillary blood sampling simple and safe. The device is activated when the user presses the button on top of the lancet. Once activated, the needle penetrates the skin and immediately retracts into the body of the device, reducing the risk of needlestick injury from an exposed needle. A dual-spring mechanism controls this action: the first spring releases the needle into the skin, and the second spring withdraws the needle back into the protective shield.

The VeriFine Safety Lancets (with push button) are available in multiple gauge and length options to accommodate different patient populations and blood volume requirements.

Only the needle component within the lancet body is provided sterile. The sterilization process has been validated according to ISO 11137-1:2006.

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

It is intended for capillary blood sampling.

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

The Indications for Use statement for the VeriFine Safey Lancet is identical to that of the predicate device (K221368). Both devices have the same intended use for obtaining capillary blood samples for diagnostic testing purposes.

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

The VeriFine Safety Lancets are substantially equivalent to the predicate device, K221368. Both devices have the same intended use for capillary blood sampling. The basic technological and operating principles are the same for both devices, utilizing a dual-spring mechanism for needle deployment and retraction. Both the subject and predicate devices are disposable, sterile, single-patient-use devices.

While certain technological differences exist between the subject and predicate devices, these differences do not raise different questions of safety and effectiveness and do not affect the fundamental design principles or safe usage of the device.

Item of description	Predicate device (K221368)	Subject device	Similarities/ Differences	Safety/Effectiveness Statement
Common name	VeriFine Safety Lancet	VeriFine Safety Lancet	N/A	N/A
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd.	Promisemed Hangzhou Meditech Co., Ltd.	Same	All produced by the same manufacturer.
Intended use	It is intended for capillary blood sampling.	It is intended for capillary blood sampling.	Same	No new concerns.
Indications for use	It is intended for capillary blood sampling.	It is intended for capillary blood sampling.	Same	No new concerns.
Target population	Not defined.	Infants (Over 6 months and Greater than 10 kg), children, adolescents, adults.	Different	The applicable population for the Verifine® Safety Lancets is adults and pediatric patients over 6 months of age (excluding neonates and newborns), as defined in accordance with the WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy (WHO, 2010). Specifically, Section 7.1.1 and Table 7.1 of the Guidelines establish age- and weight-based criteria for capillary sampling site and procedure selection, and Section 7.1.2 specifies recommended maximum lancet penetration depths by patient population — 1.5 mm for children over 6 months and under 8 years of age, and 2.4 mm for children over 8 years of age and adults. The penetration depth specifications of the Verifine® Safety Lancets are consistent with these recommended ranges for the defined population. Neonates and newborns are excluded from the intended use population, as this population requires shallower penetration depths, dedicated sharps injury prevention features, and prescription-only

				devices, none of which are characteristics of the subject device.
Anatomical site	Finger	Finger	Same	No new concerns.
Where used	Home environment, Professional Healthcare Facility	Home environment, Professional Healthcare Facility	Same	No new concerns.
Intended Users	Lay person, healthcare professional users	Lay person, healthcare professional users	Same	No new concerns.
Design	It is sterile, single use, spring loaded lancets designed for capillary blood sampling. These lancets are precision sharpened designed for maximum comfort and optimal blood flow. Safety lancets are activated when you press the device against your finger. Once activated the needle retracts into the body of the device which reduces the risk of injury as the result if an exposed needle. The first spring releases the needle into the skin and the second withdraws the needle back into the shield.	It is sterile, single use, spring loaded lancets designed for capillary blood sampling. These lancets are precision sharpened designed for maximum comfort and optimal blood flow. Safety lancets are activated when you press the button on top. Once activated the needle retracts into the body of the device which reduces the risk of injury as the result if an exposed needle. The first spring releases the needle into the skin and the second withdraws the needle back into the shield.	Similar	The subject device is activated by pressing push button on top, while the predicate device is activated by pressing device against finger. The fundamental technology and operation remain the same.
Materials (tissue-contacting)	Needle: Stainless steel; Shield: ABS; Trigger: POM; Lancet body, cap: PE;	Needle: Stainless steel (X5CrNi18-10); Shield: Polypropylene (PP); Push button: POM; Safety tab: Polyethylene (PE)	Similar	The PP shield contacts intact skin for less than one minute. PP has been used in marketed devices (e.g., K193273) and does not introduce new biocompatibility risks.
Needle gauge	18G, 21G, 23G, 25G, 26G, 28G, 30G.	Needle type: 17G, 18G, 19G, 20G, 21G, 23G, 25G, 26G, 28G, 29G, 30G, 31G, 32G, 33G. Blade type: 21G(0.8mm), 20G(0.9mm), 19G(1.1mm, 18G(1.2mm), 17G(1.5mm).	Similar	Broader needle selection provides more clinical options without introducing new risks, as the fundamental technology and operation remain the same.
Nominal needle length	1.2 mm, 1.4 mm, 1.6 mm, 1.8 mm, 2.0 mm, 2.2 mm, 2.4 mm, 2.6 mm, 2.8 mm.	Needle type: 1.2 mm, 1.5 mm, 1.6 mm, 1.8 mm, 2.0 mm, 2.2 mm, 2.4 mm, 2.8 mm, 3.0 mm. Blade type: 1.0 mm, 1.2 mm, 1.5 mm, 1.6 mm, 1.8 mm, 2.0 mm, 2.2 mm, 2.4 mm.	Similar	Broader needle selection provides more clinical options without introducing new risks, as the fundamental technology and operation remain the same.
Sterilization method	Irradiation	Irradiation	Same	No new concerns.
Sterility	SAL of 10^{-6}	SAL of 10^{-6}	Same	No new concerns.
Single use	Yes	Yes	Same	No new concerns.
Biocompatibility	Biocompatibility established	Biocompatibility established	Same	No new concerns.
Standards met	- ISO 9626:2016; - ISO 11137-1:2006; - ISO 11137-2:2013 - USP-NF M98810_01_01;	- ISO 9626:2016; - ISO 11137-1:2006; - ISO 11137-2:2013 - USP-NF M98810_01_01;	Same	No new concerns.
Compatibility with the environment and other devices	Not applicable	Not applicable	Same	No new concerns.
Energy used and/or delivered	Not applicable	Not applicable	Same	No new concerns.

Electrical safety	Not applicable	Not applicable	Same	No new concerns.
Mechanical safety	Not applicable	Not applicable	Same	No new concerns.
Chemical safety	Not applicable	Not applicable	Same	No new concerns.
Thermal safety	Not applicable	Not applicable	Same	No new concerns.
Radiation safety	Not applicable	Not applicable	Same	No new concerns.
Labeling	Labeling requirement listed in blood lancet reclassification final order (86 FR 66180) such as hand washing instruction and warning statement are supplemented.	Labeling requirement listed in blood lancet reclassification final order (86 FR 66180) such as hand washing instruction and warning statement are supplemented.	Same	No new concerns.

The subject device has the same intended use as the predicate device (K221368) for capillary blood sampling. While the subject device shares the same fundamental technological characteristics as the predicate device, certain technological differences exist as described below:

- Activation Mechanism
  Push-button activation versus pressure-against-finger activation;
- Shield Material
  Polypropylene (PP) versus Acrylonitrile Butadiene Styrene (ABS);
- Needle Gauge and Length Options
  Broader range of specifications;

These differences do not alter the fundamental operating principle, which relies on a dual-spring mechanism for needle deployment and retraction. Performance testing has demonstrated that the subject device is as safe and as effective as the predicate device.

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

The subject device has been evaluated through comprehensive nonclinical performance testing, including physical characterization (appearance, color coding, and dimensional verification per ISO 7864), mechanical testing (bond strength, spring elasticity and puncture performance per ISO 9626, and safety mechanism functionality), corrosion resistance of the stainless steel needle material, sterility testing with sterilization validation as per ISO 11137-1, ISO 11137-2, and USP <71> achieving a sterility assurance level of 10^{-6}. All testing met pre-established acceptance criteria based on applicable standards and device specifications, with no deviations observed. Puncture performance testing demonstrated equivalent performance between the subject device and the predicate device (K221368). Based on the nonclinical testing results, the subject device is as safe and effective as, and performs as well as, the predicate device.

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

No clinical testing was conducted for this submission.

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

Based on the nonclinical performance testing described above, the VeriFine Safety Lancet (subject device) has been demonstrated to be substantially equivalent to the predicate device (K221368). The subject device has the same intended use as the predicate device. While certain technological differences exist (activation mechanism, shield material, and range of gauge/length options), these differences do not raise different questions of safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate device and is appropriate for clearance under the 510(k) pathway.