February 21, 2023

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

Re: K223643
Trade/Device Name: Verifine® Ease Lancing Device, Verifine® Lancing Device
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL
Dated: November 29, 2022
Received: December 6, 2022

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 (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,

Jessica Carr -S

for Long Chen, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223643

Device Name
Verifine® Ease Lancing Device, Verifine® Lancing Device

Indications for Use *(Describe)*
It is intended to be used with disposable sterile lancets to collect capillary blood from the fingertip or alternate sites for blood glucose testing or other testing utilizing small amounts of blood. It is for single patient use only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K223643
510(k) Summary

1 Date Prepared

Nov 29th, 2022

2 Submitter's Information

Name of Sponsor:

Promisemed Hangzhou Meditech Co., Ltd.

Address:

No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, China

Contact Name:

Zearou Yang

Telephone No.:

+86 571 88772985

Fax No.:

+86 571 88772985

Email Address:

zearou.yang@promisemed.ca

3 Trade Name, Common Name, Classification

Trade/Product Name: Verifine® Ease Lancing Device, Verifine® Lancing Device

Common Name: Lancing Device

Classification name: multiple use blood lancet for single patient use only

Regulation Number: 21 CFR 878.4850

Device Class: Class II

Product Code: QRL

4 Identification of Predicate Device

K153670: Genteel Lancing Device

5 Description of the Device

The lancing device is a mechanical blood lancet holder for collecting capillary whole blood sampled from the fingertip or alternate sites. The lancing device is used with commercially available, sterile, standard square shaft blood lancets.

The lancing device is for use only on a single patient.

6 Indication

It is intended to be used with disposable sterile lancets to collect capillary blood from the fingertip or alternate sites for blood glucose testing or other testing utilizing small amounts of blood. It is for single patient use only.

7 Similarities and Differences of the Proposed Devices to the Predicate Devices

The Verifine® Ease Lancing Device, Verifine® Lancing Device are substantially equivalent to the predicate device, Genteel Lancing Device (K153670) in that these devices have same intended use and technological characteristics. The basic technological and operating principles are the same for both devices. Both the subject and predicate devices are single patient use devices. The differences above between the subject device and predicate device do not affect the basic design principle, usage of the subject device.

A detailed comparison to the predicate is provided in Table 1.

	Subject Device	Predicate Device (K153670)	Comments
Trade Name	Verifine® Ease Lancing Device, Verifine® Lancing Device	Genteel Lancing Device	
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd	Genteel, LLC	
Device Class	Class II	Class I	Different Reclassification of the device due to regulations
Product Code	QRL	FMK	Different Reclassification of the device due to regulations

Regulation number	878.4850	878.4800	Different Reclassification of the device due to regulations
Regulation Name	Blood Lancets	Manual surgical instrument for general use	Different Reclassification of the device due to regulations
Intended Use/ Indications for Use	It is intended to be used with disposable sterile lancets to collect capillary blood from the fingertip or alternate sites for blood glucose testing or other testing utilizing small amounts of blood. It is for single patient use only.	The Genteel lancing device is used with disposable sterile lancets to draw capillary blood from the fingertip or alternate sites for blood glucose testing or other testing utilizing small amounts of blood. The Genteel lancing device is for single patient use only.	Same
Use	Reusable. The lancing device is for use only on a single patient.	Reusable. The lancing device is for use only on a single patient.	Same
Non-sterile	Yes	Yes	Same
Prescribed	Over the Counter use	Over the Counter use	Same
Configuration and Materials	It is primarily made from different plastics which are both medical grades.	It is primarily made from different plastics which are both medical grades.	Same

Puncture depth settings	Verifine® Ease Lancing Device: It has varying puncture depth settings via eight adjustable settings on depth adjuster. The puncture depth ranges between 0.15mm to 1.20mm; Verifine® Lancing Device: It has varying puncture depth settings via five adjustable settings on adjusting caps. The puncture depth ranges between 0.25mm to 0.85mm.	It has varying puncture depth settings via six interchangeable contact tips on Genteel. The puncture depth is about 0.25mm to 0.55mm.	They also have varying puncture depth settings. The subject device has covered the puncture depth range of the predicate device, with more selectivity. And the epiderm thickness of human is about 0.1mm. It has penetrated the epiderm thickness to the dermis when the penetration depth is 0.15 mm, and the dermis has capillaries. Additionally, the section of "puncture depth" in the IFU clearly states that 'it is recommended to start the test from the shallowest to the deepest according to the operating instructions for the first use. If no blood is produced, select the next gear until an appropriate amount of blood is obtained.' So the safety and effectiveness of the subject device will not be affected.

Discussions of differences in technological characteristics

The subject device has the same intended use and technological characteristics as the predicate device. The differences 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.

8 Performance Testing Summary

The bench testing performed verifies that the performance of the subject device is

substantially equivalent in terms of critical performance characteristics to the predicate device.

Shipping, and Shelf-Life

- The transportation testing was conducted using lancing device product in accordance with ASTM D4169. The performance testing was conducted after simulated transportation testing. The conducted test demonstrated that there are neither damage on the packing box nor damage on the product.
- The period of validity is 5 years and it can not be used more than 3000 times, which is validated using the FDA recognized standard ASTM F1980-16.

9 Conclusion

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