June 9, 2022

Promisemed Hangzhou Meditech Co., Ltd.
℅ Wei Hsu
Regulatory Manager
Vee Care (Asia) Limited
17th Chung Pont Commercial Building, 300 Hennessy Road
Hong Kong, Hong Kong
Hong Kong

Re: K221368
Trade/Device Name: Promisemed Blood Lancet, VeriFine Safety Lancet, VeriFine Mini-Safety Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK, QRK
Dated: April 29, 2022
Received: May 12, 2022

Dear Wei Hsu:

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,

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)*
K221368

Device Name
Promisemed Blood Lancet
VeriFine Safety Lancet
VeriFine Mini-Safety Lancet

Indications for Use *(Describe)*
It 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.

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510(k) Summary

1 Date Prepared

May 9, 2022

2 Submitter's Information

Submission Sponsor:

Promisemed Hangzhou Meditech Co., Ltd.

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

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3 Trade Name, Common Name, Classification

Trade/Product Name:

Promisemed Blood Lancet

VeriFine Safety Lancet

VeriFine Mini-Safety Lancet

Common Name: Blood Lancet

Classification name:

Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature

Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature

Regulation Number: 21 CFR 878.4850

Device Class: Class II

Product Code: FMK, QRK

4 Identification of Predicate Device(s)

K192666: Promisemed Blood Lancet

VeriFine Safety Lancet

VeriFine Mini-Safety Lancet

5 Description of the Device

Promosemed Blood Lancet is a sterile, handheld, sharply-pointed, non-mechanical, scalpel-like instrument intended to be used by a healthcare provider or patient self to manually puncture the skin to obtain a small blood specimen.

VeriFine Safety lancet and **VeriFine Mini-Safety lancet** 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 designed to make taking a blood sample simple and easy. 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.

Both single-use Promisemed Blood Lancet and VeriFine Safety Lancet/VeriFine Mini-Safety Lancet offers different gauge (needle diameter) options, to allow to choose the lancet which meets blood volume needs.

6 Intended Use

It is intended for capillary blood sampling.

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

Promisemed Blood Lancet and VeriFine Safety Lancet/ VeriFine Mini-Safety Lancet are substantially equivalent to the predicate devices, K192666, in that these devices have same intended use and technological characteristics. The basic technological and operating principles are the same. The differences between the subject device and predicate device do not affect the intended use or raise new questions of safety and effectiveness.

A detailed comparison to the predicate is provided in Table 1 and Table 2.

Table 1: Device Comparison Chart for **Promisemed Blood Lancet**

	Subject Device	Predicate Device (K192666)	Significant Differences
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd	Promisemed Hangzhou Meditech Co., Ltd	
Trade Name	Promisemed® Blood Lancet	Promisemed® Blood Lancet	
Device Class	Class II	Class I (Exempt)	Different[1]
Product Code	QRK	FMK	Different[1]
Regulation number	878.8450	878.4800	Different[1]
Regulation Name	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature	Lancet, Blood	Different[1]
Intended Use/Indications for Use	It is intended for capillary blood sampling.	It is intended for capillary blood sampling.	Same
Biocompatibility	Biocompatibility established	Biocompatibility established	Same
Structure	Stainless steel needle encapsulated with a plastic body and cap, the cap is twisted off to expose the needle for use.	Stainless steel needle encapsulated with a plastic body and cap, the cap is twisted off to expose the needle for use.	Same
Material	Needle: Stainless steel Body and Cap: polyethylene	Needle: Stainless steel Body and Cap: polyethylene	Same
Single use	Yes	Yes	Same
Sterilization	Gamma	Gamma	Same
Labeling	Labeling requirement listed in blood lancet reclassification final order (86 FR 66180) such as hand washing instruction and warning statement are supplemented.	No include hand washing instruction and warning statement listed in blood lancet reclassification final order (86 FR 66180).	Different The difference does not affect the effectiveness and safety of the device.

Note 1: In response to blood lancet reclassification.

Table 2: Device Comparison Chart for **VeriFine Safety Lancet/ VeriFine Mini-Safety Lancet**

	Subject Device	Predicate Device (K192666)	Significant Differences

Manufacturer	Promisemed Hangzhou Meditech Co., Ltd	Promisemed Hangzhou Meditech Co., Ltd	
Trade Name	VeriFine Safety Lancet VeriFine Mini-Safety Lancet	VeriFine Safety Lancet VeriFine Mini-Safety Lancet	
Device Class	Class II	Class I (Exempt)	Different[1]
Product Code	FMK	FMK	Same
Regulation number	878.8450	878.4800	Different[1]
Regulation Name	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature	Lancet, Blood	Different[1]
Intended Use/Indications for Use	It is intended for capillary blood sampling.	It is intended for capillary blood sampling.	Same
Direction for use	1. Rotate the twisting cap less than half a round 2. Pull out the twisting cap 3. Place the device on the puncture site and push to start 4. Discard lancet into a sharp container 5. Press lightly on the finger toward the puncture site to obtain adequate blood sample	1. Rotate the twisting cap less than half a round 2. Pull out the twisting cap 3. Place the device on the puncture site and push to start 4. Discard lancet into a sharp container 5. Press lightly on the finger toward the puncture site to obtain adequate blood sample	Same
Gauge	18G,21G,23G,25G, 26G,28G,30G	18G,21G,23G,25G, 26G,28G,30G	Same
Needle Length (mm)	1.2, 1.4, 1.6, 1.8, 2.0, 2.2, 2.4, 2.6, 2.8	1.2, 1.4, 1.6, 1.8, 2.0, 2.2, 2.4, 2.6, 2.8	Same
Biocompatibility	Biocompatibility established	Biocompatibility established	Same
Structure/Design	VeriFine Safety Lancet and VeriFine Mini-Safety Lancet are spring-loaded lancet. VeriFine Safety lancet/ VeriFine Mini-Safety Lancet 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	VeriFine Safety Lancet and VeriFine Mini-Safety Lancet are spring-loaded lancet. VeriFine Safety lancet/ VeriFine Mini-Safety Lancet 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	Same

	needle into the skin and the second withdraws the needle back into the shield.	needle into the skin and the second withdraws the needle back into the shield.	
Material	Needle: Stainless steel Spring: Galvanized steel wire Shield, hub and Safety: ABS Trigger POM Lancet body, cap: PE	Needle: Stainless steel Spring: Galvanized steel wire Shield, hub and Safety: ABS Trigger POM Lancet body, cap: PE	Same
Single use	Yes	Yes	Same
Sterilization	Gamma	Gamma	Same
Labeling	Labeling requirement listed in blood lancet reclassification final order (86 FR 66180) such as hand washing instruction and warning statement are supplemented.	No include hand washing instruction and warning statement listed in blood lancet reclassification final order (86 FR 66180).	Different The difference does not affect the effectiveness and safety of the device.

Note 1: In response to blood lancet reclassification.

8 Performance Testing Summary

The bench testing performed verifies that the performance of the subject devices are substantially equivalent in terms of critical performance characteristics to the predicate device. These tests include:

- Visual Inspection
- Needle Dimensions
- Chemical properties
- Bond between lancet body and needle
- Resistance to corrosion of the needle
- Lancing device compatibility test (Promisemed Blood Lancet only)
- Locking function
- Spring elasticity*
- Percussive function*
- Penetrate force*

(* VeriFine Safety Lancet and VeriFine Mini-Safety Lancet only)

- Biocompatibility
  a. ISO 10993-1:2009 – Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process
  b. ISO 10993-5:2009 – Biological Evaluation of Medical Devices -- Part 5: Tests for in Vitro Cytotoxicity
  c. ISO 10993-10:2010 – Biological Evaluation of Medical Devices -- Part 10: Tests for Irritation and Skin Sensitization
- Sterility and Shelf-Life
  -ISO 11137-1:2006, Sterilization of Health Care Products - Radiation - Part 1: Requirements for Development, Validation and Routine control of a sterilization process for medical devices
  -ISO 11737-1:2006, Sterilization of Health Care Products - Microbiological Methods - Part 1: Determination of Population of Microorganisms on products
  -ISO 11737-2:2009, Sterilization of Medical Devices - Microbiological Methods - Part 2: Tests of Sterility Performed in the Definition, validation and maintenance of a sterilization process
  - Shelf life of 5 years is validated using ASTM F1980-07(2011) Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

9 Conclusion

Promisemed Blood Lancet and VeriFine Safety Lancet/VeriFine Mini-Safety Lancet has the same intended use and technological characteristics as the predicate. The labeling changes made to subject device do not raise any new or different questions of safety or effectiveness. The proposed subject device is substantially equivalent to the predicate device and is as safe and as effective as the legally marketed predicate device.