December 2, 2019

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

Re: K192666
Trade/Device Name: Promisemed Blood Lancet, VeriFine Safety Lancet, VeriFine Mini-Safety Lancet
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual Surgical Instrument for General Use
Regulatory Class: Class I
Product Code: FMK
Dated: November 15, 2019
Received: November 15, 2019

Dear Wei-Shan 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K192666

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

## 1 Date Prepared

Nov 27, 2019

## 2 Submitter's Information

**Submission Sponsor:**

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Hong Kong, China

**Contact: Wei-Shan Hsu**

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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:**

Lancet, Blood (21 CFR 878.4800, Product code FMK)

**Device Class:**

Class I

# 4 Identification of Predicate Device(s)

K113513 PLANCET blood lancet

K101145 SurgiLance® 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**

**Manufacturing aspects:**

For the Promisemed Blood Lancet, stainless steel needle is fed into an injection molding machine to over-mold plastic material (polyethylene)

forming a body and cap, encapsulating the stainless steel needles. Terminal sterilization process is performed to ensure sterility of an entire product.

The manufacturing process of the predicate device, K113513 PLANCET blood lancet, comprises injection molding of plastic needle and plastic over-molding using polyethylene (exactly the same process as involved in Promisemed Blood Lancet). The plastic needle instead of stainless steel needle is used in PLANCET blood lancet.

**Design and Functionality aspects:**

The Promisemed Blood Lancet comprises a stainless steel needle encapsulated with a plastic body and cap, the cap is twisted off to expose the needle for use. The predicate device, K113513 PLANCET blood lancet, has the exact same design and functionality as compared with Blood Lance and Safety Lancet. The difference will be instead of twisting off the cap to expose the needle, the predicate device requires the end user to pull off the cap.

**Material aspects:**

The Promisemed Blood Lancet has a needle that is made of stainless steel and a body and a cap that are made of polyethylene (PE). The stainless steel material is bio-compatible. Both the needle and the body/cap of the predicate device, K113513 PLANCET blood lancet, are made of polyethylene (PE).

## VeriFine Safety Lancet and VeriFine Mini-Safety Lancet

**Design and Functionality aspects:**

Both VeriFine Safety Lancet/VeriFine Mini-Safety Lancet and its predicate device, SurgiLance® Safety Lancet, are spring-loaded lancet and have the same basic technology characteristics for a lancet with sharps injury prevention. They are intended for piercing the skin and the indications for use are the same.

**Material aspects:**

The materials are comparable in that the needles all use medical grade stainless steel and the rest part are made of plastics materials. VeriFine Safety Lancet/VeriFine Mini-Safety Lance utilizes some of the same materials, specifically the use of medical grade stainless steel for the lancet needles, but may use different types or grades of plastics for the Shield, hub, caps, and triggers. All the materials are known biocompatible materials that have been used in lancets or other similar medical devices.

## 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

The testing performed verifies that the performance of the subject devices is substantially equivalent in terms of critical performance characteristics to the predicate device.

Cytotoxicity, Sensitization, Irritation, were performed to demonstrate biocompatibility of the patient contacting materials. Overall, the results are comparable to the predicate and support a determination of substantial equivalence.

# 9 Conclusion

Promisemed Blood Lancet and VeriFine Safety Lancet/VeriFine Mini-Safety Lancet has the same intended use and technological characteristics as the predicate. Test results demonstrate that the subject devices meet their intended use and performs as well as or better than the legally marketed predicate device. It is for these reasons that the subject devices can be found substantially equivalent.