June 8, 2022

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

Re: K221371
Trade/Device Name: Promisemed Heel Blood Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
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)*
K221371

Device Name
Promisemed Heel Blood Lancet

Indications for Use *(Describe)*
It is intended for collection of capillary blood from the heel of newborn and premature babies. The lancet has equipped with safety protection features.

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

June 8, 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 Name: Promisemed Heel Blood Lancet

Common Name: Infant Heel Lancet

Classification name:

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

Regulation Number: 21 CFR 878.4850

Device Class: Class II

Product Code: FMK

4 Identification of Predicate Device(s)

K19009 Promisemed Heel Blood Lancet

5 Description of the Device

Promisemed Heel Blood Lancet is comprised of top upper cover, bottom cover, button, safety plug, slider, rod,holder, spring, blade.The spring provides an elastic force to puncture and ensure the blade can shrink back to the covers.The blade can be fired when the spring is under pressure. The safety plug is to protect the blade from triggering before use.

Promisemed Heel Blood Lancet is single use, sterile, medical devices designed to be used in collecting the blood sample. Heel Blood Lancet is intended to be used by professionals. They are offered in various lengths (0.65mm, 0.85mm, 1.00mm, 1.50mm). The heel blood lancets are sterile (EO sterilization) and non-toxic. The product is intended for prescription (Rx) only.

6 Intended Use

It is intended for the collection of capillary blood from the heel of newborn and premature babies. The lancet has equipped with safety protection features.

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

Promisemed Heel Blood Lancet is substantially equivalent to the predicate device, K193009, 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.

	Subject Device	**Predicate Device (K193009)**	**Similarities and Differences**
Manufacturer	**Promisemed Hangzhou Meditech Co., Ltd**	**Promisemed Hangzhou Meditech Co., Ltd**	
Trade Name	**Promisemed Heel Blood Lancet**	**Promisemed Heel Blood Lancet**	
Device Class	Class II	Class I	Different[1]
Product Code	FMK	FMK	Same
Regulation number	878.8450	878.4800	Different[1]
Common Name	Infant Heel Lancet	Infant Heel Lancet	Same
Intended Use/Indications for Use	It is intended for collection of capillary blood from the heel of newborn and premature babies. The lancet has	It is intended for collection of capillary blood from the heel of newborn and premature babies. The lancet has equipped with	Same

	equipped with safety protection features.	safety protection features.	
Direction for use	1 Pull out the safety plug 2.Place the device on the puncture site and press the button to start 3. Discard the device into a sharps container 4. Using your index finger and thumb, press lightly near the puncture site to obtain an adequate blood sample	1 Pull out the safety plug 2.Place the device on the puncture site and press the button to start 3. Discard the device into a sharps container 4. Using your index finger and thumb, press lightly near the puncture site to obtain an adequate blood sample	Same
Incision Depth/ **Incision Length**	0.65mm/1.4mm 0.85mm/1.7mm 1.00mm/2.5mm 1.50mm/3.0mm	0.65mm/1.4mm 0.85mm/1.7mm 1.00mm/2.5mm 1.50mm/3.0mm	Same
Biocompatibility	Biocompatibility established	Biocompatibility established	Same
Design	1.A locking mechanism to prevent accidental activation of the device. 2.A housing that conceals the blade before and after the device is used. 3.An internal spring that automatically retracts the blade after use. 4. A stop feature that disables the device after a single use.	1.A locking mechanism to prevent accidental activation of the device. 2.A housing that conceals the blade before and after the device is used. 3.An internal spring that automatically retracts the blade after use. 4. A stop feature that disables the device after a single use.	Same
Material	Blade: Stainless steel (X6Cr13) Hull (cover): Acrylonitrile butadiene styrene (ABS) Safety plug: Polycarbonate (PC) Button: Paraformaldehyde(POM) Slider and Rod: Polycarbonate (PC) Holder: Acrylonitrile butadiene styrene (ABS) Spring: Music wire (SWPB)	Blade: Stainless steel (X6Cr13) Hull (cover): Acrylonitrile butadiene styrene (ABS) Safety plug: Polycarbonate (PC) Button: Paraformaldehyde(POM) Slider and Rod: Polycarbonate (PC) Holder: Acrylonitrile butadiene styrene (ABS) Spring: Music wire (SWPB)	Same

Single use	Yes	Yes	Same
Sterilization	EO Sterilization	EO Sterilization	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.

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. These tests include:

- Material of blade
- Appearance
- Dimensions of product
- Blade corrosion resistance
- Bond between blade and shank
- Cutting width and depth
- Safety self-locking
- Safety plug pullout
- Shooting performance
- Sterility
- Limits acidity and alkalinity
- Total heavy Metal
- Accidental access to sharp once in safe mode
- Safety mechanism activation
- Safety overriding and unlocking force after activation
- 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 11135:2014, Sterilization of health-care products-Ethylene oxide-Requirements for the development, validation and routine control of a sterilization process for medical devices

-Sterile Barrier Packaging Testing performed on the proposed device:

- Visual Inspection ASTM F1886/F1886M
- Seal strength ASTM F88/F88-15
- Dye penetration ASTM F1929-15

- Shelf life of 5 years is validated using ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

9 Conclusion

The Promisemed Heel Blood Lancet has the same intended use, the principle of operation and technical characteristics as the predicate device. 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.