December 3, 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: K193009
Trade/Device Name: Promisemed Heel Blood Lancet
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual Surgical Instrument for General Use
Regulatory Class: Class I
Product Code: FMK
Dated: October 15, 2019
Received: October 28, 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)*
K193009

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.

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."

510(k) Summary

1 Date Prepared

Nov 27, 2019

2 Submitter's Information

Submission Sponsor:

Promisemed Hangzhou Meditech Co., Ltd.

No. 12, Longtan Road, Cangqian Street, Yuhang District,

Hangzhou City,311121 Zhejiang, China

Contact: Zearou Yang

Telephone No.: +86 571 88772985

Fax No.:+86 571 88772985

Email: zearou.yang@promisemed.ca

Submission Correspondent:

Vee Care (Asia) Limited

17F Chung Pont Commercial Building, 300 Hennessy Road,

Hong Kong, China

Contact: Wei-Shan Hsu

E-mail: ws@vee.com.hk

3 Trade Name, Common Name, Classification

Trade Name:

Promisemed Heel Blood Lancet

Common Name:

Infant Heel Lancet

Classification name:

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

Device Class:

Class I

4 Identification of Predicate Device(s)

K130132 BabyLance Heel Incision Device

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

Similarities-

The Promisemed Heel Blood Lancet employs the same technology and use comparable blade and housing materials as the predicate device.

Differences-

Though Promisemed Heel Blood Lancet utilizes different materials, they deliver the same safety and performance features. The differences 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 to effectiveness and safety.

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

The testing performed verifies that the performance of the subject device 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

The Promisemed Heel Blood Lancet has the same intended use, the principle of operation and technical characteristics as the predicate device. Test results demonstrate that the subject device meets its intended use and performs as well as or better than the legally marketed predicate device. It is for these reasons that the subject device can be found substantially equivalent.