August 26, 2021

SteriLance Medical (Suzhou) Inc.
% Joyce Yang, Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan
Times Square, Nanshan District
Shenzhen, Guangdong 518000
China

Re: K210745
Trade/Device Name: Heel Incision Safety Lancet
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual Surgical Instrument for General Use
Regulatory Class: Class I
Product Code: FMK
Dated: July 8, 2021
Received: July 26, 2021

Dear Joyce 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 and Part 809); 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)*
K210745

Device Name
Heel Incision Safety Lancet

Indications for Use *(Describe)*
Heel Incision Safety Lancet is intended for the collection of capillary blood from the heel of newborn, preemie, and toddler. 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

510(k) Number: K210745

Date of Summary prepare: August 11, 2021

1. Submission Sponsor

Applicant Name	SteriLance Medical(Suzhou) Inc.
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Contact person	Yuan Jie
Phone	+86-512-65799308

2. Submission correspondent

Name	Shenzhen Joyantech Consulting Co., Ltd
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Post Code	518000
Phone No.	+86-755-86069197
Contact Person	Joyce Yang
Email	joyce@cefda.com

3. Device Identification

Type of 510(k) submission:	Traditional
Trade Name:	Heel Incision Safety Lancet
Common name:	Lancet, Blood
Regulation name:	Manual Surgical Instrument for General Use
Review Panel:	General & Plastic Surgery
Product Code:	FMK
Device Class:	I
Regulation Number:	21 CFR 878.4800

4. Legally Marketed Predicate Device

Trade Name	Promisemed Heel Blood Lancet
Regulation number	21 CFR 878.4800
Regulation class	I
Regulation name	Manual Surgical Instrument for General Use
510(k) Number	K193009
Product Code	FMK
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd.

5. Device Description

Heel Incision Safety 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.

Heel Incision Safety Lancet is single use, sterile medical devices designed to be used in collecting the blood sample. Heel Incision Safety Lancet is intended to be used by professionals.

Heel Incision Safety Lancets are sterile and non-toxic. The product is intended for prescription (Rx) only.

6. Intended Use/ Indications for Use

Heel Incision Safety Lancet is intended for the collection of capillary blood from the heel of newborn, preemie, and toddler. The lancet has equipped with safety protection features.

7. Technological characteristics comparison

Comparison item	Subject Device: Heel Incision Safety Lancet	Predicate Device: Promisemed Heel Blood Lancet (K193009)
Product Code	FMK	FMK
Regulation Number	21 CFR § 878.4800	21 CFR § 878.4800
Classification	Class I	Class I
Type of use	Prescription Use	Prescription Use
Intended use & Indications for Use	Heel Incision Safety Lancet is intended for the collection of capillary blood from the heel of newborn, preemie, and toddler. The lancet has equipped with safety protection features.	It is intended for collection of capillary blood from the heel of newborn and premature babies. The lancet has equipped with safety protection features.
Applicable user	Newborn, preemie,and toddler	Newborn, preemie
Safety protection features	Yes	Yes
Reuse durability	Single use	Single use
Sterilization method and SAL	Sterilized by Radiation SAL=10^{-6}	Sterilized by ethylene oxide SAL=10^{-6}

Comparison item	Subject Device: Heel Incision Safety Lancet	Predicate Device: Promisemed Heel Blood Lancet (K193009)
Self life	5 Years	5 Years
Incision length and depth	Depth*Length: 0.65*1.40mm, 0.85*1.75mm 1.00*2.50mm, 1.14*2.80mm, 2.00*3.00mm	Depth*Length: 0.65*1.50mm, 0.85*1.75mm, 1.00*2.50mm, 1.50*3.00mm
Component	1. Triggering button 2. Safety button/Screw button 3. Spring 4. Cam 5. Lancet core 6. Shell 7. Blade 8. Swing arm	1. Top upper cover 2. Bottom cover 3. Button 4. Safety plug 5. Slider 6. Rod 7. Holder 8. Spring 9. blade
Materials of parts in contact with human body	Blade:304 stainless steel Shell: ABS Triggering button: ABS Safety button: ABS	Blade: 304 stainless steel Shell: ABS Triggering button: ABS Safety button: ABS

The subject device and the predicate device have the same intended use, similar technology characteristics, and similar ingredients. The differences will not cause safety and effectiveness problems for proposed device, and does not affect the equality.

8. Summary of non-clinical testing

*Performance Testing

The bench testing performed verifies that the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device in terms of critical performance characteristics . These tests are as follow.

Items	**Results**
Material of blade	F type stainless steel materials
Appearance	The surface has no burr and scratch
Dimensions of product	The height of product(mm): 32±1.5 The width of product(mm)：:35±1.5
Blade corrosion resistance	No blemishes
Force to activate Safety Screw button	Compared with equivalent devices, there was

Items	Results
	no statistical difference
Trigger force	Compared with equivalent devices, there was no statistical difference
Safety overriding and unlocking force after activation	Compared with equivalent devices, there was no statistical difference
Sterility	Sterile
Limits acidity and alkalinity	Meet the requirement
Total heavy metal	Meet the requirement
Incision depth and length	All models have been tested within tolerances
Safety self-locking	There were no failures observed in a test run of 500 devices
Safety plug pullout	There were no failures observed in a test run of 500 devices
Shooting performance	There were no failures observed in a test run of 500 devices
Accidental access to sharp once in safe mode	There were no failures observed in a test run of 500 devices

***Biocompatibility**

The biocompatibility evaluations were conducted in accordance with the 2020 FDA Guidance document *Use of International Standard ISO 10993-1 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process"* . The tests include the following tests:

Item	Test method	Test results
In Vitro Cytotoxicity	ISO 10993-5: 2009	No Cytotoxicity
Skin Sensitization	ISO 10993-10: 2010	No Skin sensitization
Intracutaneous reactivity	ISO 10993-10: 2010	No irritation
Acute Systemic Toxicity Test	ISO 10993-11: 2017	No Acute Systemic Toxicity
Material mediated	USP<151>	Absence of pyrogens

pyrogenicity		
In vitro Hemolytic	ASTM F756-17	No Hemolytic

9. Brief discussion of clinical tests

No clinical tests were performed.

10. Conclusions

The conclusion drawn from the nonclinical tests demonstrates that the subject device, the Heel Incision Safety Lancets are as safe and effective, and performs as well as or better than the legally marketed predicate device cleared under K193009.