August 31, 2022

SteriLance Medical (Suzhou) Inc.
Ms. Susan Sun
Manager
No.168 PuTuoShan Road, New District
Suzhou, Jiangsu 215153
China

Re: K221507
Trade/Device Name: Disposable Blood Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRK,QRL
Dated: July 28, 2022
Received: August 4, 2022

Dear Ms. Sun:

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,

for

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)*
K221507

Device Name
Disposable Blood Lancet

Indications for Use *(Describe)*
Disposable Blood Lancet is used for capillary blood collection.

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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"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

Date of Summary prepare: August 31, 2022

1. Submission Sponsor

Applicant Name	SteriLance Medical (Suzhou) Inc.
Address	No.168 PuTuoShan Road, New District, 215153 Suzhou, Jiangsu, P.R.China
Contact person	Susan Sun
Phone	+86-512-65799308

2. Submission correspondent

Name	SteriLance Medical (Suzhou) Inc.
Address	No.168 PuTuoShan Road, New District, 215153 Suzhou, Jiangsu, P.R.China
Post Code	215153
Phone No.	+86-512-65799308
Contact Person	Susan Sun
Email	registration2@sterilance.com

3. Device Identification

Type of 510(k) submission:	Traditional
Trade Name:	Disposable Blood Lancet
Model:	Soft
Classification name:	Lancet, Blood
Review Panel:	General & Plastic Surgery
Product Code:	QRK, QKL
Device Class:	II
Regulation Number:	21 CFR 878.4850

4. Legally Marketed Predicate Device

Trade Name	Promisemed Blood Lancet
Regulation number	21 CFR 878.4800
Regulation class	I
Regulation name	Manual Surgical Instrument for General Use
510(k) Number	K192666
Product Code	FMK
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd.

5. Device Description

Disposable Blood Lancet is a single use, sterile medical device designed to be used for capillary blood collection. The device comprises a stainless needle encapsulated with a plastic needle body and protective cap, the protective cap is twisted off to expose the needle for use.

The device was sterilized by Radiation. The needle body and protective cap form a sterile barrier to maintain the needle sterile.

6. Intended Use/ Indications for Use

Disposable Blood Lancet is used for capillary blood collection.

7. Technological characteristics comparison

Comparison item	Subject Device: Disposable Blood Lancet (K221507)	Predicate Device: Promisemed Blood Lancet (K192666)	Comments
Product Code	QRK, QKL	FMK	Different [1]
Regulation Number	21 CFR § 878.4850	21 CFR § 878.4800	Different[1]
Classification	Class II	Class I	Different [1]
Type of use	OTC	OTC	Same
Intended use & Indications for Use	Disposable Blood Lancet is used for capillary blood collection.	It is intended for capillary blood sampling.	Same
Applicable user	Adult and pediatric	Adult and pediatric	Same
Reuse durability	Single use	Single use	Same
Sterilization method and SAL	Sterilized by Radiation SAL=10^{-6}	Sterilized by Radiation SAL=10^{-6}	Same
Shelf life	5 Years	3 Years	Different [2]
Component	Needle, Needle body, and Protective cap	Needle, Needle body, and Cap	Same

Comparison item	Subject Device: Disposable Blood Lancet (K221507)	Predicate Device: Promisemed Blood Lancet (K192666)	Comments
Specification (needle diameter)	21G, 23G, 26G, 28G, 30G, 32G, 33G	Contain a variety of gauge (unknown the detail)	Similar
Materials	Needle: stainless steel Needle body and cap: Polyethylene	Needle: stainless steel Needle body and cap: Polyethylene	Same

Different [1] : On November 22, 2021, FDA reclassified blood lancet, therefore, the product code, regulation number and classification are different.

Different [2] : The shelf life of the subject device is different from the predicate device. The shelf life of the subject device has been verified in accordance with ASTM F1980, demonstrating that the performance of the device and the integrity of the sterile barrier remain stable over the claimed 5-year shelf life. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

Similar: In ISO 9626, the needle size is designated by nominal diameter, corresponding gauge size. Gauge size ranges from 10G-34G. The difference in gauge size does not affect intended use. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

8. Summary of non-clinical testing

***Performance Testing**

The bench testing performed verifies that the performance of the proposed device is substantially equivalent in terms of critical performance characteristics to the predicate device. These tests are as follow:

- Appearance and Cleanliness and Needle tip appearance
- Needle dimension, Exposed length of product
- Cap site, Needle tip sharpness and Binding Strength
- Double needles, Empty needle and Reverse needle
- Compatibility test between Disposable blood lancet and Lancing Device

***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 result
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	ISO 10993-11: 2017	No Acute Systemic Toxicity
Material-Mediated Pyrogenicity	ISO 10993-11: 2017	Absence of pyrogen

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 Disposable Blood Lancets are as safe and effective, and performs as well as or better than the legally marketed predicate device cleared under K192666.