January 16, 2024

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

Re: K233796
Trade/Device Name: Disposable safety lancet (Impress); Disposable safety lancet (Impress Pro); Disposable safety lancet (Lite4); Disposable blood lancet (Elite); Disposable blood lancet (Elite Pro)
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: November 17, 2023
Received: November 29, 2023

Dear Susan 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.01.16 14:42:34 -05'00'

Mark Trumbore, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

Disposable safety lancet (Impress);
Disposable safety lancet (Impress Pro);
Disposable safety lancet (Lite4);
Disposable blood lancet (Elite);
Disposable blood lancet (Elite Pro)

Indications for Use *(Describe)*

The disposable safety lancet is used for capillary blood collection.
The device has an integral sharps injury prevention feature.

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

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2023/11/17

1. Submission sponsor

Name: SteriLance Medical (Suzhou) Inc.
Address: No.168 PuTuoShan Road, New District,215153 Suzhou, Jiangsu, P. R. China
Contact person: Susan Sun
Title: Deputy Quality Manager
E-mail: registration@sterilance.com
Tel: 86-15957138921

2. Subject Device Information

Trade/Device Name	Disposable Safety Lancet
Model	Impress; Impress Pro; Elite; Elite Pro; Lite4
Common Name	Blood Lancet
Regulatory Class	Class II
Classification	21CFR 878.4850 / Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature / FMK
Submission type	Traditional 510(K)

3. Predicate Device

SteriLance Medical (Suzhou) Inc., Disposable Safety Lancet under K221521.

4. Device Description

The Disposable Safety Lancets produced is sterile, single use, spring loaded lancets designed for capillary blood sampling. The device intended for a single use that is comprised of a single use blade attached to a solid, non-reusable base (including an integral sharps injury prevention feature) that is used to puncture the skin to obtain a drop of blood for diagnostic purposes. The integral sharps injury prevention feature allows the device to be used once and then renders it inoperable and incapable of further use.
The device is intended to be used by professionals and lay person.

5. Intended use & Indication for use

The disposable safety lancet is used to obtain capillary blood samples. The device has an integral sharps injury prevention feature.

6. Comparison to the Predicate Device

Features	Subject Device: Disposable Safety	Predicate Device: Disposable	Comparison

	Lancet	Safety Lancet (K221521)	
Product Code	FMK	FMK	Same
Regulation Number	21 CFR § 878.4850	21 CFR § 878.4850	Same
Classification	Class II	Class II	Same
Type of use	OTC	OTC	Same
Indications for Use	The disposable safety lancet is used to obtain capillary blood samples. The device has an integral sharps injury prevention feature	The disposable safety lancet is used to obtain capillary blood samples. The device has an integral sharps injury prevention feature	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
Gauge	17;18;21;23;25;26;28;30	17;18;21;23;26;28;30	Different
Penetration depth (mm)	Impress& Impress Pro& Elite Pro& Lite4 1.2, 1.5, 1.8, 2.0, 2.2, 2.3, 2.4, 2.8mm	1.2, 1.3, 1.5, 1.8, 2.0, 2.2, 2.3, 2.4, 2.8mm	Same
	Elite 1.2, 1.4, 1.5, 1.6, 1.8, 2.0, 2.2, 2.3, 2.4, 2.8mm		Different
Component	Needle Shell Press button Protective cap	Needle Shell Press button Protective cap	Same
Materials of parts in contact with human body	Needle:304 stainless steel	Needle:304 stainless steel	Same

Different: The physical dimension difference does not raise any safety and effectiveness questions. The needle diameter and penetration depth were verified in the performance test report.

7. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the proposed device was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The battery of testing included

the following tests:

- Cytotoxicity
- Skin Sensitization
- Intracutaneous reactivity
- Acute systemic toxicity

Non-clinical data

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:

- Appearance and type, Cleanliness
- Basic Dimensions
- Needle Diameter, sharpness and triggering depth
- Safety, Single-use and adjustment function

8. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed subject device is substantially equivalent to the predicate device.