February 26, 2025

SteriLance Medical (Suzhou) Inc.
Susan Sun
Quality Manager
No.168 PuTuoShan Road, New District
Suzhou, Jiangsu 215253
China

Re: K244031
Trade/Device Name: Disposable Blood Lancet (Soft Pro); Disposable Blood Lancet (Softsure); Disposable Blood Lancet (Softsure Pro); Disposable Blood Lancet (Softsense)
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRK
Dated: December 23, 2024
Received: December 30, 2024

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

James H. Jang -S
Digitally signed by James H. Jang -S
Date: 2025.02.26 21:52:11 -05'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K244031

Device Name

Disposable Blood Lancet (Soft Pro);
Disposable Blood Lancet (Softsure);
Disposable Blood Lancet (Softsure Pro);
Disposable Blood Lancet (Softsense)

Indications for Use *(Describe)*

Disposable Blood Lancet is used for capillary blood sampling.

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.

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510(K) Summary - K244031

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2024/12/11

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: Quality Manager
E-mail: registration@sterilance.com
Tel: 86-0512-65799308 Ext 8301

2. Subject Device Information

Trade/Device Name	Disposable Blood Lancet
Model	Softsure, Softsure Pro, Softsense, Soft Pro
Common Name	Blood Lancet
Regulatory Class	Class II
Classification	21CFR 878.4850 QRK (Single use only blood lancet without an integral sharps injury prevention feature) QRL (Multiple use blood lancet for single patient use only)
Submission type	Traditional 510(K)

3. Predicate Device

SteriLance Medical (Suzhou) Inc., Disposable Blood Lancet, under K221507.

4. Device Description

Disposable Blood Lancet is a single use, sterile medical device designed to be used for capillary blood sampling. 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.

5. Intended use & Indication for use

Disposable Blood Lancet is used for capillary blood sampling.

6. Comparison to the Predicate Device

Features	Subject Device: Disposable Blood Lancet	Predicate Device: Disposable Blood Lancet (K221507)	Comparison
Product Code	QRK; QRL	QRK；QRL	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	Disposable Blood Lancet is used for capillary blood sampling.	Disposable Blood Lancet is used for capillary blood collection	Similar
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	21G, 23G, 26G, 28G, 30G, 32G, 33G	21G, 23G, 26G, 28G, 30G, 32G, 33G	Same
Component	Needle Needle body Protective cap	Needle Needle body Protective cap	Same
Exposed Needle Length	Soft Pro; Softsure; Softsure Pro 3.20±0.60mm	3.20±0.60mm	Different
	Softsense: 2.50±0.60mm		
Penetration Depth	Depend on the Puncture depth of Compatible lancing device.	Depend on the Puncture depth of Compatible lancing device.	Same
Materials of parts in contact with human body	Needle: stainless steel Needle body and cap: Polyethylene	Needle: stainless steel Needle body and cap: Polyethylene	Same

Similar: The intended use is same. The subject device is used for draw capillary blood and regulated under 21 CFR 878.4850 . The difference does not raise any safety and effectiveness questions.

Different: The physical dimension difference does not raise any safety and effectiveness questions. The Exposed Needle Length 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, 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

8. Conclusion

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