June 12, 2026

SteriLance Medical (Suzhou), Inc.
Susan Sun
Primary Correspondent
#168 Putuoshan Rd.
New District
Suzhou, Jiangsu 215153
China

RE: K261634
Trade/Device Name: Disposable Blood Lancet (Soft)
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood lancets
Regulatory Class: Class II
Product Code: QRK
Dated: May 17, 2026
Received: May 18, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.06.12 08:02:58 -04'00'

Colin Kejing Chen, Ph.D.
Acting 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.

510(k) Number *(if known)*
K261634

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 – K261634

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: June 11, 2026

1. Submitter

Name: SteriLance Medical (Suzhou) Inc.
Address: No.168 PuTuoShan Road, New District, 215153 Suzhou, Jiangsu, P. R. China
Contact person: Susan Sun
Title: Regulatory Affairs Manager
E-mail: registration@sterilance.com
Tel: 86-0512-65799308 Ext 8301

2. Subject Device Information

Trade/Device Name	Disposable Blood Lancet
Model	Soft
Common Name	Blood Lancet
Regulatory Class	Class II
Classification Name	Single Use Only Blood Lancet without an Integral Sharps Injury Prevention Feature
Product Code	QRK
Regulation Number	21 CFR 878.4850

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 for capillary blood collection. The device comprises a stainless needle encapsulated within a plastic needle body and protective cap, both of which are made of polyethylene. Prior to use, the protective cap is twisted off to expose the needle tip. The device is sterilized by gamma irradiation, achieving a sterility assurance level (SAL) of 10^{-6}. The needle body, which encapsulates the stainless steel needle through an injection molding process, forms the sterile barrier system that maintains needle sterility up to the point of use.

5. Indication for Use

Disposable Blood Lancet is used for capillary blood collection.

6. Technological Characteristics Comparison

Comparison item	Subject Device: Disposable Blood Lancet	Predicate Device: Disposable Blood Lancet（K221507）	Comments
Product Code	QRK	QRK	No change.
Manufacturer	SteriLance Medical (Suzhou) Inc.	SteriLance Medical (Suzhou) Inc.	No change.
Regulation Number	21 CFR § 878.4850	21 CFR § 878.4850	No change
Classification	Class II	Class II	No change
Type of use	OTC	OTC	No change
Intended use & Indications for Use	Disposable Blood Lancet is used for capillary blood collection.	Disposable Blood Lancet is used for capillary blood collection.	No change
Applicable user	Adult and pediatric	Adult and pediatric	No change
Reuse durability	Single use	Single use	No change
Sterilization method and SAL	Sterilized by gamma irradiation $SAL=10^{-6}$	Sterilized by gamma irradiation $SAL=10^{-6}$	No change
Shelf life	5 Years	5 Years	No change
Component	Needle, needle body, and protective cap	Needle, needle body, and protective cap	No change
Specification (needle diameter)	21G, 23G, 25G, 26G, 28G, 30G, 31G, 32G, 33G	21G, 23G, 26G, 28G, 30G, 32G, 33G	Difference[1]
Materials	Needle: stainless steel Needle body and cap: Polyethylene	Needle: stainless steel Needle body and cap: Polyethylene	No change
Biocompatibility	Complied with ISO 10993 series standards	Complied with ISO 10993 series standards	No change
Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	No change

Difference[1]: The difference in needle gauge specifications between the subject and predicate devices, specifically, the addition of 25G and 31G, does not raise new questions of safety or effectiveness. Both gauge sizes fall within the range of commercially available lancet specifications, and the addition of these gauges does not alter the device's intended use, design, operating principle, sterilization method, or sterile barrier system.

Summary of Non-clinical Testing

All non-clinical testing conducted on the subject device was designed to demonstrate that the Disposable Blood Lancet is substantially equivalent to the predicate device (Disposable Blood Lancet, K221507) with respect to critical performance characteristics. Test setup and execution were conducted in accordance with applicable standards. The following performance data were generated to support the substantial equivalence determination.

Performance Testing

Bench testing was conducted on the subject device to demonstrate that its critical performance characteristics are substantially equivalent to those of the predicate device. All test results have met the applicable acceptable criteria.

- Product appearance and configuration
- Needle cap position
- Basic dimensions
- Steel needle diameter
- Exposed needle length
- Bonding firmness test
- Needle tip sharpness
- Double needle, inverted needle, and empty needle
- Cleanliness
- Biological safety

Biocompatibility

The biocompatibility of the subject device was evaluated in accordance with FDA's guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*. All tests passed, and the results are considered applicable to the subject device:

- Cytotoxicity
- Skin sensitization
- Intracutaneous reactivity
- Acute systemic toxicity
- Material-mediated pyrogenicity

7. Conclusions

Based on the totality of the evidence in this submission, including the comparison of Indications for Use, the comparison of technological characteristics, and the performance testing results, the subject device is substantially equivalent to the predicate device. The non-clinical testing demonstrates that the subject device performs as safely and effectively as the predicate device with all evaluated performance characteristics and biocompatibility endpoints. The addition of 25G and 31G needle gauges does not introduce new questions of safety or effectiveness relative to the predicate device.