August 30, 2022

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

Re: K221970
Trade/Device Name: Lancing device
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL
Dated: June 22, 2022
Received: July 5, 2022

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 (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)*
K221970

Device Name
Lancing device

Indications for Use *(Describe)*
Lancing device is used with disposable blood lancet to obtain capillary blood samples.

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

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2022/6/20

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 9294

2. Subject Device Information

Trade/Device Name	Lancing device
Model	LDE; LDE AST; LDE4; LDE4 AST; NanoSense; OneStep
Common Name	Lancing device
Regulatory Class	Class II
Classification	21CFR 878.4850 / Multiple use blood lancet for single patient use only / QRL
Submission type	Traditional 510(K)

3. Predicate Device

ACON Laboratories, Inc., On call® Lancing device under K113332.

4. Device Description

Lancing device is used with disposable blood lancet to obtain capillary blood samples. It has multiple penetration depth levels, normally 6 or 9. Lancing device is for single patient use only.

5. Intended use & Indication for use

Lancing device is used with disposable blood lancet to obtain capillary blood samples.

6. Comparison to the Predicate Device

Comparison item	Subject Device:Lancing device	Predicate Device: On call® Lancing device (K113332)	Comparison
Product code	QRL	NBW	Different[1]
Regulation code	21CFR 878.4850	21CFR 862.1345	Different[1]
Classification	Class II	Class II	Same
Type of use	OTC	OTC	Same

<table>
<tr><td>Intended use & indications for use</td><td>Lancing device is used with the disposable blood lancet to obtain capillary blood samples.</td><td>The On Call® Lancing Device is used with On Call® disposable sterile lancets to draw capillary blood from the fingertip, palm (at the base of the thumb) or forearm, for blood glucose testing or other testing utilizing small amounts of blood. The On Call® Lancing Device is intended to be used by a single patient and should not be shared.</td><td>Similar</td></tr>
<tr><td>Reuse durability</td><td>Multi use for single patient</td><td>Multi use for single patient</td><td>Same</td></tr>
<tr><td>Self life</td><td>5years</td><td>5years</td><td>Same</td></tr>
<tr><td>Depth adjustment</td><td>Puncture depth requirement (Unit：mm)
<table>
<tr><th>Model</th><th>LDE</th><th>LDE4</th><th>NanoSense</th><th>OneStep</th></tr>
<tr><td>1-gear</td><td>0.60±0.30</td><td>0.50±0.30</td><td>0.80±0.30</td><td>0.60±0.30</td></tr>
<tr><td>1.5-gear</td><td>/</td><td>0.70±0.30</td><td>0.95±0.30</td><td>0.75±0.30</td></tr>
<tr><td>2-gear</td><td>0.90±0.30</td><td>0.90±0.30</td><td>1.10±0.30</td><td>0.90±0.30</td></tr>
<tr><td>2.5-gear</td><td>/</td><td>1.10±0.30</td><td>1.25±0.30</td><td>1.05±0.30</td></tr>
<tr><td>3-gear</td><td>1.20±0.30</td><td>1.30±0.30</td><td>1.40±0.30</td><td>1.20±0.30</td></tr>
<tr><td>3.5-gear</td><td>/</td><td>1.50±0.30</td><td>1.55±0.30</td><td>1.35±0.30</td></tr>
<tr><td>4-gear</td><td>1.50±0.30</td><td>1.70±0.30</td><td>1.70±0.30</td><td>1.50±0.30</td></tr>
<tr><td>4.5-gear</td><td>/</td><td>1.90±0.30</td><td>1.85±0.30</td><td>1.65±0.30</td></tr>
<tr><td>5-gear</td><td>1.80±0.30</td><td>2.10±0.30</td><td>2.00±0.30</td><td>1.80±0.30</td></tr>
<tr><td>6-gear</td><td>2.10±0.30</td><td>/</td><td>/</td><td>/</td></tr>
<tr><td colspan="5">The puncture depth of LDE AST and LDE4 AST is more than 1.1mm which is Non adjustable depth.</td></tr>
</table></td><td>6 gear
Puncture depth Requirement (Unit:mm)
<table>
<tr><td>Gear 1</td><td>0.60mm±0.30mm</td></tr>
<tr><td>Gear 2</td><td>0.90mm±0.30mm</td></tr>
<tr><td>Gear 3</td><td>1.20mm±0.30mm</td></tr>
<tr><td>Gear 4</td><td>1.50mm±0.30mm</td></tr>
<tr><td>Gear 5</td><td>1.80mm±0.30mm</td></tr>
<tr><td>Gear 6</td><td>2.10mm±0.30mm</td></tr>
</table></td><td>Different[2]</td></tr>
<tr><td>Mechanical loading</td><td>Spring-driven</td><td>Spring-driven</td><td>Same</td></tr>
<tr><td>Puncture sites</td><td>Fingertip
Palm （AST end cap）
Forearm (AST end cap)</td><td>Fingertip
Palm
Forearm</td><td>Same</td></tr>
<tr><td>Materials of parts in</td><td>Priming barrel: ABS
Ejector: POM</td><td>Plastic composition: ABS
Clear cap: Transparent</td><td>Different[3]</td></tr>
</table>

contact with human body	Lancet holder: ABS Trigger button: ABS Adjusting head inner core: ABS Out cover: ABS End Cap: ABS AST end cap: PS	ABS	

Different[1]: The classification and Regulation number are different because FDA issued the final order about Reclassification of Blood Lancets on 11/22/2021.

Similar: The intended use is same. The subject device is draw capillary blood from the fingertip, and use AST end cap can draw capillary blood from palm or forearm. The difference does not raise any safety and effectiveness questions.

Different[2]: The puncture depth adjustment difference does not raise any safety and effectiveness questions. The puncture depth was verified in the performance test report.

Different[3]: The raw materials of proposed devices may be different from the predicate devices.

However, all the materials are known biocompatible materials that have been used in lancing device or other similar medical devices.

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

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 Printing appearance
- Basic Dimensions
- Compatible performance
- Bounce performance
- Puncture performance
- Adjustable performance
- Lancet unloading performance

8. Conclusion

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