July 6, 2026

SteriLance Medical (Suzhou), Inc.
Susan Sun
Quality Manager
#168 Putuoshan Rd., New District
Suzhou, Jiangsu 215253
China

Re: K260122
Trade/Device Name: Lancing Device (PressGo, LDE3, LDE3AST, LDE5, EasyStep)
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL
Dated: June 12, 2026
Received: June 12, 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: 2026.07.06 23:38:15 -04'00'

Colin K. 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260122

Please provide the device trade name(s).

Lancing Device (LDE3, LDE3 AST, LDE5, PressGo, EasyStep)

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2026/03/31

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	PressGo; LDE3; LDE3 AST; LDE5; EasyStep
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

SteriLance Medical (Suzhou) Inc., LDE; LDE AST; LDE4; LDE4 AST; NanoSense; OneStep Lancing Device, under K221970.

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 table between the subject devices and the predicate devices			
Comparison item	Subject Device:Lancing device	Predicate Device: Lancing device (K221970)	Comparison
Manufacturer	SteriLance Medical (Suzhou) Inc.	SteriLance Medical (Suzhou) Inc.	Same

<table>
<tr><td>Product code</td><td>QRL</td><td>QRL</td><td>Same</td></tr>
<tr><td>Regulation code</td><td>21CFR 878.4850</td><td>21CFR 878.4850</td><td>Same</td></tr>
<tr><td>Classification</td><td>Class II</td><td>Class II</td><td>Same</td></tr>
<tr><td>Type of use</td><td>OTC</td><td>OTC</td><td>Same</td></tr>
<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>Lancing device is used with the disposable blood lancet to obtain capillary blood samples.</td><td>Same</td></tr>
<tr><td>Product model</td><td>PressGo, LDE 3, LDE3 AST, LDE5, EasyStep</td><td>LDE, LDE AST, LDE4, LDE4 AST, NanoSense, OneStep</td><td>Difference</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>5 years</td><td>5 years</td><td>Same</td></tr>
<tr><td>Depth adjustment</td><td>Puncture depth requirement (Unit：mm)
<table>
<tr><th>Model</th><th>LDE3</th><th>PressGo, LDE5, EasyStep</th></tr>
<tr><td>1-gear</td><td>0.60±0.30</td><td>0.60±0.30</td></tr>
<tr><td>1.5-gear</td><td>/</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></tr>
<tr><td>2.5-gear</td><td>/</td><td>1.05±0.30</td></tr>
<tr><td>3-gear</td><td>1.20±0.30</td><td>1.20±0.30</td></tr>
<tr><td>3.5-gear</td><td>/</td><td>1.35±0.30</td></tr>
<tr><td>4-gear</td><td>1.50±0.30</td><td>1.50±0.30</td></tr>
<tr><td>4.5-gear</td><td>/</td><td>1.65±0.30</td></tr>
<tr><td>5-gear</td><td>1.80±0.30</td><td>1.80±0.30</td></tr>
<tr><td>6-gear</td><td>2.10±0.30</td><td>/</td></tr>
<tr><td colspan="3">The puncture depth of LDE3 AST is more than 1.1mm which is Non adjustable depth.</td></tr>
</table></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>Similarly:
The subject device's depth adjustment is identical across the predicate device. Performance tests address these differences, ensuring no impact on design principles, usage, effectiveness, or safety.</td></tr>
<tr><td>Mechanical loading</td><td>Spring-driven</td><td>Spring-driven</td><td>Same</td></tr>
</table>

Puncture sites	Fingertip Palm （AST end cap） Forearm (AST end cap)	Fingertip Palm （AST end cap） Forearm (AST end cap)	Same
Materials of parts in contact with human body	Priming barrel: ABS Ejector: POM Lancet holder: ABS Trigger button: ABS Adjusting head inner core: ABS Out cover: ABS End Cap: ABS, PC AST end cap: PS	Priming barrel: ABS Ejector: POM Lancet holder: ABS Trigger button: ABS Adjusting head inner core: ABS Out cover: ABS End Cap: ABS AST end cap: PS	Difference: The subject devices' has added PC material and has undergone biocompatibility testing in accordance with ISO 10993. The product's PC material has undergone disinfection efficacy and cyclic testing validation.
Biocompatibility testing	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Same
Performance Testing	Appearance Type and Basic dimension Laser marking appearance Compatible performance Bounce performance Puncture performance Adjustable performance Lancet unloading performance	Appearance Basic dimension Printing appearance Compatible performance Bounce performance Puncture performance Adjustable performance Lancet unloading performance	Similarly: The printing process of the Logo is different, and this difference does not affect the effectiveness and safety of the device.
Label/Labeling	Complied with 21 CFR 878.4850 (c)(2)	Complied with 21 CFR 878.4850 (c)(2)	Same

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
- Pyrogenicity

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
- Type and basic dimension
- Compatible performance
- Bounce performance
- Puncture performance
- Adjustable performance
- Lancet unloading performance
- Laser marking appearance

8. Conclusion

The lancing device have the same indications for use as the predicate devices listed above. Any minor differences in the technological characteristics of the subject device when compared to the predicate devices have been successfully evaluated through appropriate safety and performance testing which demonstrates that the subject device, when compared to the predicate device, does not raise any new questions of safety and effectiveness.