11/23/2022

i-SENS, Inc.
H.S. Yoo
Regulatory Affairs Assistant Manager
43, Banpo-Daero 28-Gil, Seocho-Gu,
Seoul, Seoul 06646
Korea, South

Re: K222656
Trade/Device Name: LDE4 Lancing Device
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL
Dated: September 27, 2022
Received: September 28, 2022

Dear H.S. Yoo:

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,

Jessica Carr -S

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)*
K222656

Device Name
LDE4 Lancing device

Indications for Use *(Describe)*
LDE4 lancing device is used with a disposable blood lancet to obtain a capillary blood sample from the fingertip for testing utilizing small amounts of blood.

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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"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

Prepared in accordance with the requirements of 21 CFR 807.92

1. Applicant Information

Name	: i-SENS, Inc.
Address	: 43, Banpo-Daero 28-Gil, Seocho-Gu, Seoul, Korea 06646
Applicant Contact	: H.S. Yoo / Regulatory Affairs Specialist
Correspondent	i-SENS, Inc., 43, Banpo-Daero 28-Gil, Seocho-Gu, Seoul, Korea 06646
E-mail	: hsyoo@i-sens.com
Telephone number	: +82-2-910-0516
Prepared Date	: September 27, 2022

2. Manufacturer Information

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

3. Medical Device Information

Device Name	: LDE4 Lancing Device
Common name	: Lancing device, Blood lancet
Regulation Number	: 21CFR 878.4850, Multiple use blood lancet for single patient use only
Class	: Class II
Product Code	: QRL
Submission Type	: Special 510(k)

4. Predicate Device Information

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

5. Device Description

LDE4 Lancing device is used with a disposable blood lancet to obtain a capillary blood sample from the fingertip for testing utilizing small amounts of blood. It has nine levels of penetration depths. LDE4 lancing device is compatible with CareSens lancets, Soft series disposable blood lancet from SteriLance and most other blood lancets.

6. Intended Use, Indications for Use

LDE4 Lancing device is used with a disposable blood lancet to obtain a capillary blood sample from the fingertip for testing utilizing small amounts of blood.

7. Technological characteristics compared to the predicate device

	Candidate device: LDE4 Lancing Device	**Predicate Device: On Call® Lancing device**	**Comparison**
Product code	QRL	FMK, NBW	Different [1]
Regulation number	878.4850	878.4850, 862.1345	Different [1]
Classification	Class II		Same
Intended use &Indications for use	LDE4 Lancing device is used with a disposable blood lancet to obtain a capillary blood sample from the fingertip for testing utilizing small amounts of blood.	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	Same

<table>
<tr><td></td><td></td><td>amounts of blood. The On call ® Lancing Device is intended to be used by a single patient and should not be shared.</td><td></td></tr>
<tr><td>Shelf life</td><td colspan="2">5 years</td><td>Same</td></tr>
<tr><td>Depth adjustment</td><td>9 levels by twisting cap
<table><tr><th>Penetration level</th><th>Depth (mm)</th></tr><tr><td>1</td><td>0.5 ± 0.3</td></tr><tr><td>1.5</td><td>0.7 ± 0.3</td></tr><tr><td>2</td><td>0.9 ± 0.3</td></tr><tr><td>2.5</td><td>1.1 ± 0.3</td></tr><tr><td>3</td><td>1.3 ± 0.3</td></tr><tr><td>3.5</td><td>1.5 ± 0.3</td></tr><tr><td>4</td><td>1.7 ± 0.3</td></tr><tr><td>4.5</td><td>1.9 ± 0.3</td></tr><tr><td>5</td><td>2.1 ± 0.3</td></tr></table></td><td>6 levels by twisting cap
<table><tr><th>Penetration level</th><th>Depth (mm)</th></tr><tr><td>1</td><td>0.6 ± 0.3</td></tr><tr><td>2</td><td>0.9 ± 0.3</td></tr><tr><td>3</td><td>1.2 ± 0.3</td></tr><tr><td>4</td><td>1.5 ± 0.3</td></tr><tr><td>5</td><td>1.8 ± 0.3</td></tr><tr><td>6</td><td>2.1 ± 0.3</td></tr></table></td><td>Same

The deepest penetration depth is the same</td></tr>
<tr><td>Mechanical loading</td><td colspan="2">Spring-driven</td><td>Same</td></tr>
<tr><td>Puncture sites</td><td>Fingertip</td><td>Fingertip
Palm
Forearm</td><td>Different [2]</td></tr>
<tr><td>Materials of parts in contact with human body</td><td>Priming barrel: ABS
Ejector: POM
Lancet holder: ABS
Trigger button: ABS
Adjusting head inner core: ABS
Out cover: ABS
End Cap: ABS</td><td>Plastic composition: ABS
Clear cap: Transparent ABS</td><td>Different [3]</td></tr>
<tr><td>Disinfectant used for cleaning</td><td>Clorox Healthcare Bleach Germicidal Wipes (EPA. 67619-12)</td><td>DisCide Ultra Disinfecting Wipes (EPA. 10492-4)</td><td>Different [4]</td></tr>
</table>

Different [1]: According to the FDA final order to reclassify blood lancets.

Different [2]: Only to obtain capillary blood samples from the fingertip.

Different [3]: Includes a POM part, which is a known biocompatible material that have been validated for biocompatibility, cleaning and disinfection.

Different [4]: Disinfectant validated in the cleaning and disinfection validation.

8. Performance Data

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

8.1 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 testing
- Skin sensitization
- Intracutaneous reactivity

8.2 Cleaning and Disinfection Validation

Virus elimination efficacy tests were performed on the surface materials of the LDE4 lancing device (ABS and POM), and a robustness test was performed on the LDE4 lancing device using Clorox Healthcare Bleach Germicidal Wipes; EPA registration # 67619-12 (Active ingredient: Sodium hypochlorite (0.55%)).

The validation results demonstrated complete inactivation of Hepatitis B Virus (HBV) on the surface materials of the lancing device. Robustness test results also demonstrated that there was no change in performance or physical appearance in the surface materials of the lancing device after 260 cleaning and 260 disinfection cycles (520 in total) designed to simulate cleaning and disinfection to support 5 years of single-patient use.

8.3 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
- Basic dimensions
- Compatible performance
- Bounce performance
- Puncture Test
- Adjustable performance
- Lancet unloading performance

9. Conclusion

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