10/28/2022

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

Re: K221521
Trade/Device Name: Disposable Safety Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: September 30, 2022
Received: October 3, 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)*
K221521

Device Name
Disposable Safety Lancet

Indications for Use *(Describe)*
The disposable safety lancet is used to obtain capillary blood samples. The device has an integral sharps injury prevention feature

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.

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K221521 510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2022/10/25

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: Deputy Quality Manager
E-mail: registration1@sterilance.com
Tel: 86-0512-65799308 Ext 8301

2. Subject Device Information

Trade/Device Name	Disposable Safety Lancet
Model	Press, Press Plus, Press2, Press2 Plus, Lite3, Flex3
Common Name	Blood Lancet
Regulatory Class	Class II
Classification	21CFR 878.4850 / Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature / FMK
Submission type	Traditional 510(K)

3. Predicate Device

Promisemed Hangzhou Meditech Co., Ltd., Promisemed Blood Lancet, VeriFine Safety Lancet, VeriFine Mini-Safety Lancet under K192666.
Reference device: MediPurpose Pte. Ltd., The Surgilance® Safety Lancet under K101145.

4. Device Description

The disposable safety lancet is sterile, single use, spring loaded and designed to draw a capillary blood sample. The device is mainly comprised of a single use needle/blade attached to a needle core by injection molding and then assembled with spring, press button, depth adjusting ring (optional) and shell parts, which also forming an integral sharps injury prevention feature. The device is used to puncture the skin to obtain a drop of blood for testing purposes. The integral sharps injury prevention feature allows the device to be used once and then renders it inoperable and incapable of further use.
Flex 3 model is the only adjustable lancet, and all other models (Press, Press Plus, Press2, Press2 Plus, Lite3) are provided at various single depths.
The device is intended to be used by professionals and individuals.

5. Intended use & Indication for use

The disposable safety lancet is used to obtain capillary blood samples. The device has an integral sharps injury prevention feature

6. Comparison to the Predicate Device

Features	Subject Device: Disposable Safety Lancet	Predicate Device: VeriFine Safety Lancet (K192666)	Comparison
Product Code	FMK	FMK	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	The disposable safety lancet is used to obtain capillary blood samples. The device has an integral sharps injury prevention feature	It is intended for capillary blood sampling.	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	17;18;21;23;26;28;30	21;23;26;28;30;31;32	Different There are some differences in the smaller gauge specification compared with the predicate device. The comparative Performance testing can demonstrate the safety and performance of the subject device.
Penetration depth (mm)	1.2, 1.5, 1.8, 2.0, 2.2, 2.3, 2.4, 2.8	1.6, 1.8, 2.0, 2.2, 2.3, 2.4	Different. More wide range of penetration depth in the device will not cause new safety and effectiveness concerns raised. The comparative Penetration testing can demonstrate the safety and performance of the subject device.
Component	Needle Shell Press button Protective cap	Needle Shell Press button Protective cap	Same

Materials of parts in contact with human body	Needle:304 stainless steel	Needle:304 stainless steel	Same

Comparison to Reference Device

Features	Subject Device: Disposable Safety Lancet	Reference Device: The Surgilance® Safety Lancet (K101145)	Comparison
Penetration depth (mm)	1.2, 1.5, 1.8, 2.0, 2.2, 2.3, 2.4, 2.8	1.0, 1.8, 2.2, 2.3, 2.8,	Different. The range of penetration depth is within the reference device.

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
- Pyrogen
- Hemocompatibility

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
- Needle Diameter, sharpness and triggering depth
- Safety, Single-use and adjustment function

8. Conclusion

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