February 20, 2026

Ningbo Medsun Medical Co., Ltd.
Ping Liu
Regulation Affairs Manager
298 Huangjipu Rd., Jiangbei,
Ningbo, Zhejiang 315031
China

Re: K253605
Trade/Device Name: Safety Heel Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: January 23, 2026
Received: January 23, 2026

Dear Ping Liu:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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: 2026.02.20 09:31:10 -05'00'

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

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.	K253605

Please provide the device trade name(s).

Safety Heel Lancet

Please provide your Indications for Use below.

The Safety Heel Lancet is a single use device with a sterile blade that is used by medical professionals to obtain a blood sample from the heel of neonates and infants.

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

1.Date Prepared

February 19, 2026

2.Submitter

Ningbo Medsun Medical Co., Ltd.

No. 298 Huangjipu Road, Jiangbei, 315031,Ningbo, P.R.China

Contact Person: Liu Ping, Regulation Affairs Manager

Tel: +86-574-86301887/ Fax:+86-574-86301887

Date Prepared: February 19, 2026

3.Device

Trade Name: Safety Heel Lancet

Common Name:Blood Lancets

Classification Name:Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature

Regulation Number:21 CFR 878.4850

Regulatory Class: II

Product Code: FMK

Review Panel: General & Plastic Surgery

4.Predicate Device

Manufacturer: SteriLance Medical (Suzhou) Inc.

Device Name: Heel Incision Safety Lancet

510(k) Number: K210745

5.Device Description

Safety Heel Lancet, could be divided into Model D and Model E according to the shape of the trigger lock.The difference of Model D and Model E is that trigger lock of Model D doesn't need to be broke before use, trigger lock of Model E need to be broke before use.

Safety Heel Lancet is composed of housing, trigger lock, trigger button, blade, blade holder, slider, side cover and spring. The material of blade is X65Cr13 stainless steel, the

material of spring is 304 stainless steel, the other plastic parts are ABS.The blade is ejected and retracted by a mechanical structure to realize blood sampling.There is an integrated automatic inactivation system of the device to prevent device reuse. After the protection system is activated, the blade will be permanently retracted into the housing and cannot be restored to the activated state to avoid accidental injury to personnel.Therefore, the device cannot be re-used.It has sharps injury protection feature that it can reduce the occurrence of accidental needlesticks.

Safety Heel Lancet is sterilized by Gamma ray(e-beam) and for single use.It is designed to be used by medical professionals to obtain a blood sample from the heel of neonates and infants.

Safety Heel Lancet is sterile and non-toxic. The device is intended for prescription (Rx) only.

6.Indications for Use

The Safety Heel Lancet is a single use device with a sterile blade that is used by medical professionals to obtain a blood sample from the heel of neonates and infants.

7.Comparison of Technological Characteristics With the Predicate Device

Description	Subject Device (Model D)	Subject Device (Model E)	Predicate Device (K210745)	Remark
Product Code	FMK	FMK	FMK	Same
Regulation Number	21CFR 878.4850	21CFR 878.4850	21CFR 878.4850	Same
Indications for use	The Safety Heel Lancet is a single use device with a sterile blade that is used by medical professionals to obtain a blood sample from the heel of neonates and infants.	The Safety Heel Lancet is a single use device with a sterile blade that is used by medical professionals to obtain a blood sample from the heel of neonates and infants.	Heel Incision Safety Lancet is intended for the collection of capillary blood from the heel of newborn, preemie, and toddler. The lancet has equipped with safety protection features.	Similar (Note 1)
Prescription/ over-the counter use	Prescription use	Prescription use	Prescription use	Same
Target patient populations	Newborns and infants	Newborns and infants	Newborn, preemie,and toddler	Similar (Note 2)

Sterilization	Irradiation Sterilization SAL:10^{-6}	Irradiation Sterilization SAL:10^{-6}	Irradiation sterilized, SAL: 10^{-6}	Same
Biocompatibility	Meet the requirements of ISO 10993 series standards	Meet the requirements of ISO 10993 series standards	Meet the requirements of ISO 10993 series standards	Same
Safety protection features	Yes	Yes	Yes	Same
Reuse or single use	Single use	Single use	Single use	Same
Composition	Housing, trigger lock, trigger button, blade, blade holder, slider, side cover and spring	Housing, trigger lock, trigger button, blade, blade holder, slider, side cover and spring	1.Triggering button; 2.Safety button/Screw button;3.Spring;4.Cam 5.Lancet core;6.Shell 7.Blade;8.Swing arm	Similar (Note 3)
Materials	Blade:X65Cr13 stainless steel Spring:304 stainless steel Other plastic parts:ABS	Blade:X65Cr13 stainless steel Spring:304 stainless steel Other plastic parts:ABS	Blade: 304 stainless steel Shell: ABS Triggering button: ABS Safety button: ABS	Different (Note 4)
Blade cutting depth/width	Cutting depth: 0.65±0.25 mm 0.85±0.25 mm 1.00±0.25 mm 1.50±0.3 mm Cutting width: 1.50±0.5 mm 1.75±0.5 mm 2.50±0.5 mm 2.80±0.5 mm	Cutting depth: 0.65±0.25 mm 0.85±0.25 mm 1.00±0.25 mm 1.50±0.3 mm Cutting width: 1.50±0.5 mm 1.75±0.5 mm 2.50±0.5 mm 2.80±0.5 mm	Depth*Length: 0.65*1.40 mm, 0.85*1.75 mm 1.00*2.50 mm, 1.14*2.80 mm, 2.00*3.00 mm	Similar (Note 5)

Note 1:The indications for use of the subject device is similar as the predicate device.

They are all used for collection of capillary blood from the heel. The used patients of the subject device are neonates and infants, the used patients of the predicate device are newborn,preemie and toddler, the two descriptions are different but the essence is consistent.Therefore,the difference will not affect the safety and effectiveness of the product.

Note 2:The target patient populations of the subject device is similar as the predicate device.

They are explained in the indications for use mentioned above.Therefore,the difference will

not affect the safety and effectiveness of the product.

Note 3:The composition of the subject device is similar as the predicate device. Although the names are different, the actual composition is consistent.Therefore,the difference will not affect the safety and effectiveness of the product.

Note 4:The materials of the subject device is different as the predicate device. However, all the materials are known biocompatible materials that have been used in the subject device. The biocompatibility report proves the safety of the material.Therefore,the difference will not affect the safety and effectiveness of the product.

Note 5:The blade cutting depth/width of the subject device is similar as the predicate device. The cutting depth is in the range of 0.65-1.50 mm and the cutting width is in the range of 1.50-2.80 mm of the subject device. They are all within the range of the predicate device(depth:0.65-2.00 mm, width:1.40-3.00 mm).Therefore,the difference will not affect the safety and effectiveness of the product.

8.Performance Testing Summary

Performance Test

All non-clinical bench testing performed on the subject device is to demonstrate the substantial equivalence to the predicate devices. Tests setup and execution are performed in accordance with corporate standard, which is formulated according to relevant standards and product characteristics. Results of the testing are demonstrating the compliance to the standards and matching the performance of the subject device to the predicate devices.

The following items of non-clinical performance bench testing are provided in support of the substantial equivalence determination.

×Dimension

×Appearance

×Compatibility

×Connection secureness

×Blade sharpness

×Blade cutting depth/width

×Blade surface roughness

×Blade hardness

×Blade elasticity

×Retractability

×Sterile

×Activation of the sharps injury protection mechanism-Trigger force 5.2 of ISO 23908

×The security of safety mode protection - resistance to external 5.3 a) of ISO 23908

×The safety of safety mode protection-minimizing accidental contact 5.3 b) of ISO 23908

×The safety protected by the safe mode - free fall resistance 5.3 c) of ISO 23908

Biocompatibility Test

The subject device meets the requirements of ISO 10993 series standards, and the following items are evaluated:In vitro cytotoxicity, skin sensitization, intracutaneous reactivity, acute systemic toxicity and pyrogen. The results show that the product has good biocompatibility.The following biocompatibility data is provided in support of the substantial equivalence.

Items	Requirements	Result
In vitro cytotoxicity	ISO 10993-5: 2009	Pass
Skin sensitization	ISO 10993-10: 2021	Pass
Intracutaneous reactivity	ISO 10993-23:2021	Pass
Acute Systemic toxicity	ISO 10993-11:2017	Pass
Pyrogen	ISO 10993-11: 2017 USP <151>	Pass

Performance of Clinical Simulated Use Testing for Sharps Injury Protection

According to ISO 23908:2011 Sharps injury protection-Requirements and test methods-Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling and Guidance for Industry and FDA Staff-Medical Devices with Sharps Injury Prevention Features, we have completed the test of clinical simulated use testing for sharps injury protection.

9.Conclusions

Based on device comparison information and non-clinical bench testing, the subject device is substantially equivalent to the predicate devices (K210745).