August 28, 2024

Ningbo Medsun Medical Co., Ltd.
Ping Liu
Regulation Affairs Manager
No. 298 Huangjipu Road, Jiangbei
Ningbo, Zhejiang 315031
China

Re: K242316
Trade/Device Name: Safety Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: August 1, 2024
Received: August 5, 2024

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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,

Long H. Chen -S Digitally signed by Long H. Chen -S
Date: 2024.08.28 14:10:26 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242316

Device Name

Safety Lancet

Indications for Use *(Describe)*

Safety Lancet is intended to be used to obtain capillary blood sample to perform medical testing, including blood glucose monitoring and for tests using 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.

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510(k) Summary

1.Date Prepared

August 1st, 2024

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: August 1st, 2024

3.Device

Trade Name: Safety 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: Ningbo Medsun Medical Co., Ltd.

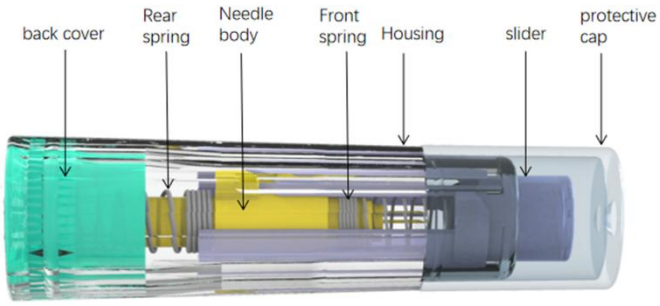
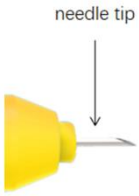
Device Name: Safety Lancet

510(k) Number: K222090

5.Device Description

Safety Lancet, could be divided into Model XY, Model XH and Model XA according to the design features and key functional elements.The device is sterilized by Gamma ray(Co-60 or e-beam) and for single use.The shelf life is 5 years.

Product Structure of the Safety Lancet are summarized in the table below:

Model	Design features / key functional elements
Model XY 	Model XY is composed of a protective cap, a slider, a front spring, housing, needle body with tri-bevel edge needle or blade, a rear spring and a back cover. The needle body with needle or blade is hidden inside the housing/slider. The housing is colour coded for different versions. Parts and components of Model XY:   Note: The right picture shows a partial enlarged view of the needle tip which is hidden inside the housing/slider. Automatic inactivation mechanism: There is an integrated automatic inactivation system to prevent lancet reuse. When the slider is pressed, the slider pushes the two bosses of the needle holder backwards. The bosses move backwards over the short rib on the inner side of the housing, and the rear spring is pressed and activated to launch the needle forwards for blood sampling. The needle retracts automatically back into the housing after the puncture, due to the force from the pressed front spring. The needle cannot go back to the starting position and stays between the relaxed rear spring and front spring. Therefore, the device cannot be re-used. The automatic inactivation mechanism is illustrated below: Before use (left) / After use (right)

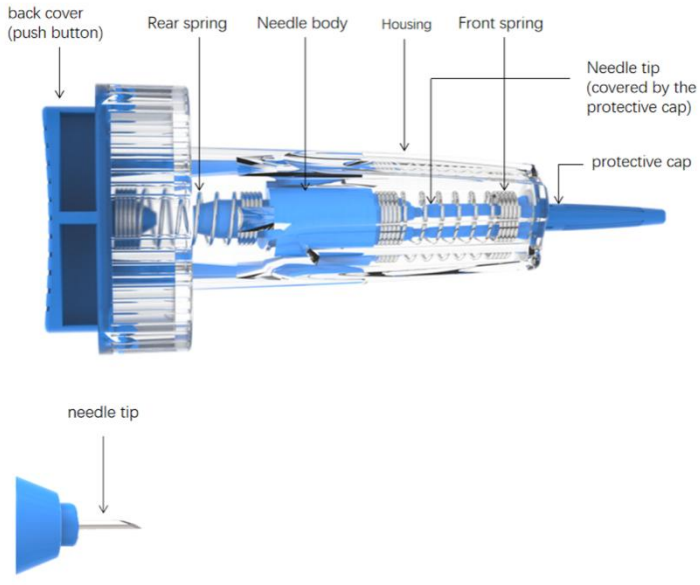
Design features:

- For capillary blood sampling
- No pre-loading required
- Contact activated safety lancet
- Protective cap designed to prevent accidental activation
- Pre-activated safety feature
- Automatic needle retraction immediately after use
- Automatically inactivated system to prevent lancet reuse
- Needle fully shielded before and after use
- Sterile, single use

Model XH

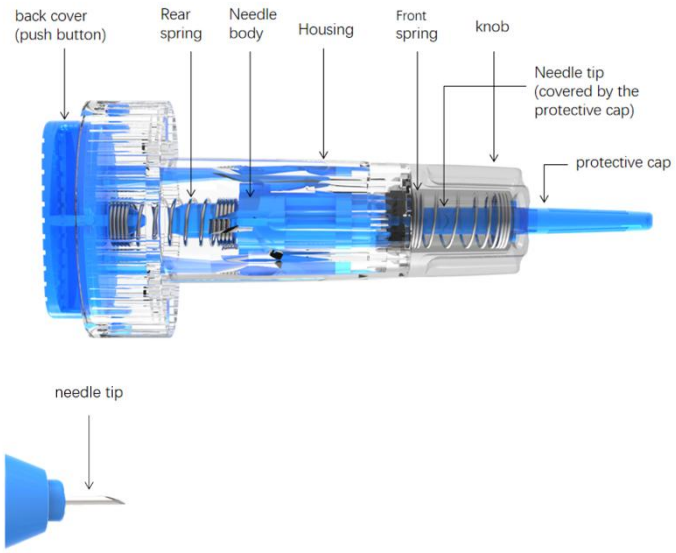
Model XH is composed of a protective cap, a front spring, housing, needle body with tri-bevel edge needle or blade, a rear spring and a back cover (push button). The needle body with needle or blade is hidden inside the housing/protective cap. The device is colour coded for different versions.

Parts and components of Model XH:



Note: The right picture shows a partial enlarged view of the needle tip which is hidden inside the housing/protective cap.

	Automatic inactivation mechanism: There is an integrated automatic inactivation system to prevent lancet reuse. When the slider is pressed, the slider pushes the two bosses of the needle holder backwards. The bosses move backwards over the short rib on the inner side of the housing, and the rear spring is pressed and activated to launch the needle forwards for blood sampling. The needle retracts automatically back into the housing after the puncture, due to the force from the pressed front spring. The needle cannot go back to the starting position and stays between the relaxed rear spring and front spring. Therefore, the device cannot be re-used. The automatic inactivation mechanism is illustrated below: Before use (left) / After use (right)  Design features: • For capillary blood sampling • No pre-loading required • Push button activated safety lancet • Pre-activated safety feature • Automatic needle retraction immediately after use • Automatically inactivated system to prevent lancet reuse • Needle fully shielded before and after use • Sterile, single use
Model XA 	Model XA is composed of a protective cap, a knob (for depth settings), a front spring, housing, needle body with tri-bevel edge needle, a rear spring and a back cover (push button). The needle body with needle or blade is hidden inside the housing/protective cap. The device is colour coded for different versions. Parts and components of Model XA:



Note: The right picture shows a partial enlarged view of the needle tip which is hidden inside the housing/protective cap.

Automatic inactivation mechanism:

There is an integrated automatic inactivation system to prevent lancet reuse. When the slider is pressed, the slider pushes the two bosses of the needle holder backwards. The bosses move backwards over the short rib on the inner side of the housing, and the rear spring is pressed and activated to launch the needle forwards for blood sampling. The needle retracts automatically back into the housing after the puncture, due to the force from the pressed front spring. The needle cannot go back to the starting position and stays between the relaxed rear spring and front spring. Therefore, the device cannot be re-used. The automatic inactivation mechanism is illustrated below:

Before use (left) / After use (right)

Design features:

- For capillary blood sampling
- No pre-loading required

	• Push button activated safety lancet • Pre-activated safety feature • Automatic needle retraction immediately after use • Automatically inactivated system to prevent lancet reuse • Adjustable penetration depth • Needle fully shielded before and after use • Sterile, single use

6.Indications for Use

Safety Lancet is intended to be used to obtain capillary blood sample to perform medical testing, including blood glucose monitoring and for tests using small amounts of blood.

7.Comparison of Technological Characteristics With the Predicate Device

Description	Subject Device	Predicate Device (K222090)	Remark
Product Code	FMK	FMK	Same
Regulation Number	21CFR 878.4850	21CFR 878.4850	Same
Indications for use	Safety Lancet is intended to be used to obtain capillary blood sample to perform medical testing, including blood glucose monitoring and for tests using small amounts of blood.	Safety Lancet is intended to be used to obtain capillary blood sample to perform medical testing, including blood glucose monitoring and for tests using small amounts of blood.	Same
Prescription/over -the counter use	Over-the counter use	Over-the counter use	Same
Design	There is an integrated automatic inactivation system to prevent lancet reuse. When the slider is pressed, the slider pushes the two bosses of the needle holder backwards. The bosses move backwards over the short rib on the inner side of the housing, and the rear spring is pressed and activated to launch the needle forwards for blood	There is an integrated automatic inactivation system to prevent lancet reuse. When the slider is pressed, the slider pushes the two bosses of the needle holder backwards. The bosses move backwards over the short rib on the inner side of the housing, and the rear spring is pressed and activated to launch the needle forwards for blood	Same

	sampling. The needle retracts automatically back into the housing after the puncture, due to the force from the pressed front spring. The needle cannot go back to the starting position and stays between the relaxed rear spring and front spring. Therefore, the device cannot be re-used.	sampling. The needle retracts automatically back into the housing after the puncture, due to the force from the pressed front spring. The needle cannot go back to the starting position and stays between the relaxed rear spring and front spring. Therefore, the device cannot be re-used.	
Materials	The safety lancet are composed needle/ blade,silicone oil,spring and plastic part(back cover,slider,housing and protective cap).	The safety lancet are composed needle/ blade,silicone oil,spring and plastic part(back cover,slider,housing and protective cap).	Same
Model	The safety lancet has Model XY,Model XH and Model XA. The different model is distinguished by the appearance, needle diameter/blade, penetration depth and color.	The safety lancet has Model XY,Model XH and Model XA. The different model is distinguished by the appearance, needle diameter/blade, penetration depth and color.	Same
Performance	Dimension,Appearance,Needle-tip,Drop performance,Trigger force,Corrosion resistance feature, Retractable,Penetration Depth,Challenge Safe Mode-Resistance, Challenge Safe Mode-Needle Tip Exposed, Anti-activation test, Self-destruct performance test,pH and total heavy metal,Bacterial Endotoxins	Dimension,Appearance,Needle-tip,Drop performance,Trigger force,Corrosion resistance feature, Retractable,Penetration Depth,Challenge Safe Mode- Resistance, Challenge Safe Mode-Needle Tip Exposed, Anti-activation test, Self-destruct performance test,pH and total heavy metal,Bacterial Endotoxins	Same

Sterilization	Irradiation Sterilization SAL:10^{-6}	Irradiation sterilized, SAL: 10^{-6}	Same
Labeling	Conform with 21 CFR 801	Conform with 21 CFR 801	Same
Biocompatibility	Meet the requirements of ISO10993 series standards, and the following tests are performed:In vitro cytotoxicity, skin sensitization,intracutaneous reactivity, acute systemic toxicity, and pyrogen.	Meet the requirements of ISO10993 series standards, and the following tests are performed:In vitro cytotoxicity, skin sensitization,intracutaneous reactivity, acute systemic toxicity, and pyrogen.	Same
Reuse or single use	Single use	Single use	Same
Dimension/ gauge, penetration depth	Model XY Dimension/gauge: 21G,23G,25G,26G,28G, 30G(Needle type), 1.2mm(Blade type) Penetration depth: 1.4mm-2.8mm(Needle type), 1.6mm-2.0mm (Blade type)	Model XY Dimension/gauge: 21G,23G,25G,26G,28G, 30G(Needle type), 1.2mm(Blade type) Penetration depth: 1.4mm-2.8mm(Needle type), 1.6mm-2.0mm (Blade type)	Same
	Model XH Dimension/gauge: 18G,19G,20G,21G,22G, 23G,24G,25G,26G,27G, 28G,29G,30G,31G,32G, 33G(Needle type), 1.5mm (Blade type) Penetration depth: 0.7mm-2.8mm(Needle type),1.6mm -2.0mm(Blade type)	Model XH Dimension/gauge: 18G,21G,23G,28G (Needle type), 1.5mm (Blade type) Penetration depth: 1.2mm-2.8mm(Needle type),1.6mm -2.0mm(Blade type)	Different (Note 1)
	Model XA Dimension/gauge: 18G,19G,20G,21G,22G, 23G,24G,25G,26G,27G, 28G,29G,30G,31G,32G, 33G(Needle type) Penetration depth:	Model XA Dimension/gauge: 21G,23G,28G (Needle type) Penetration depth: 1.3mm/1.8mm/2.3mm,1.5 mm/2.0mm/2.5mm(Needl	Different (Note 2)

	1.3mm/1.8mm/2.3mm,1.5mm/2.0mm/2.5mm(Needle type); The specification of 1.3mm/1.8mm/2.3mm penetration depth is named version XA5; The specification of 1.5mm/2.0mm/2.5mm penetration depth is named version XA11.	e type); The two specifications of penetration depth is named version XA1.	

Note 1: The dimension/gauge of the subject device is more than the predicate device. The version XH1 of the predicate device is not including 19G/20G/22G/24G/25G/26G/ 27G/29G/ 30G/31G/32G/33G, which are including in the version XH1 of the subject device.The needle gauge of subject device is a widely used in the market and meet the requirements ISO 9626:2016. The penetration depth of the subject device is getting shorter than the predicate device. The shortest penetration depth is changed from 1.2mm to 0.7mm, it means the The length of puncture entering the skin is shorter, which will reduce patient's pain and there is no standard for regulating the penetration depth.Therefore,the difference will not affect the safety and effectiveness of the product.

Note 2:The predicate device of Model XA only has one version XA1, which has two specifications(each specification has three penetration depth that can be adjusted, 1.3mm/1.8mm/ 2.3mm and 1.5mm/2.0mm/ 2.5mm). The subject device of Model XA has two versions-XA5 and XA11. The version XA5 has the specification of 1.3mm/1.8mm/ 2.3mm penetration depth, the version XA11 has the specification of 1.5mm/2.0mm/ 2.5mm penetration depth. This is a change of name rule,which is more clear for version. Other, The dimension/gauge of the subject device is more than the predicate device. The version XA1 of the predicate device is not including 18G/19G/20G/22G/24G/25G/26G/27G/29G/30G/ 31G/32G/33G, which are including in the version XA5/XA11of the subject device.The needle gauge of subject device is a widely used in the market and meet the requirements ISO 9626:2016. Therefore, the difference will not affect the safety and effectiveness of the product.

8.Performance Testing Summary

Performance Test

The subject device has the substantially equivalent technological characteristics as the predicate device cleared under K222090.We has verified the design of the subject device as part of its design control process in accordance with the Quality System Regulation. This testing included appearance,needle-tip,dimension,penetrating force and penetration depth according to the following standards:

▲ISO 9626 Stainless steel needle tubing for the manufacture of medical devices, and to performance

▲ISO 7864 Sterile hypodermic needles for single use-Requirements and test methods

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 subject device has well biocompatibility.

Therefore,the change of this 510(k) does not introduce critical differences or new risks to the intended use of the device.

9.Conclusions

Based on device comparison information and non-clinical bench testing, the subject device is substantially equivalent to the predicate devices (K222090).