October 30, 2024

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

Re: K242627
Trade/Device Name: Safety Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: August 28, 2024
Received: September 3, 2024

Dear Liu Ping:

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.

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.10.30 10:36:21 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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Infection Control Devices
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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)*

K242627

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 28st, 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

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Date Prepared: August 28st, 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 XA Pro and Model ZF.Each model has sharps protection features that it can reduce the occurrence of accidental needle sticks. The device is sterilized by Co-60 or e-beam gamma ray and for single use.The shelf life is 5 years. Model XA Pro has four versions according to the different three penetration depths, version XA1 Pro,version XA3 Pro,version XA5 Pro and version XA11 Pro. Model ZF also

has four versions according to the different need type and material of slider, version ZF1,version ZF2,version ZF1 Blade and version ZF2 Blade.

Model XA Pro 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.There is an integrated automatic inactivation system to prevent lancet reuse. When the back cover is pressed down, it drives the rear spring to compress downwards. The back cover support legs are flush with the inclined surface of the protruding line head of the housing. The needle is rotated and slided downwards under the force of the rear spring until it is disengaged from the inclined surface and fired forward for blood sampling, while compressing the front spring.The needle will be retracted 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.

Model ZF lancet is composed of spring, three-facet needle or blade, housing, and slider. The needle body with needle or blade is concealed within housing/slider. The lancets of different specifications are in different colors. There is an integrated automatic inactivation system to prevent lancet reuse. The spring is fixed at the bottom of the housing, and when the slider is pressed down, which drives the spring to compress downwards.The two locking points(blocked the needle) on the slider will be opened along the slope of the housing, the needle will be released to fire under the force of the spring for blood sampling. After the puncture is completed, the spring retracts to a relaxed state and synchronously pulls the needle body back into the housing. Therefore, the device cannot be re-used.

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 (Model XA Pro)	Subject Device (Model ZF)	Predicate Device (K222090)	Remark
Product Code	FMK	FMK	FMK	Same

Regulation Number	21CFR 878.4850	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.	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	Over-the counter use	Same
Design	There is an integrated automatic inactivation system to prevent lancet reuse. The spring is fixed at the bottom of the housing, and when the slider is pressed down, which drives the spring to compress downwards.The two locking points(blocked the needle) on the slider will be opened along the slope of the housing, the needle will be released to fire under the force of the spring for blood sampling. After the puncture is completed, the spring retracts to a relaxed state and synchronously pulls the needle body back into the housing. Therefore, the device cannot be re-used.	There is an integrated automatic inactivation system to prevent lancet reuse. When the back cover is pressed down, it drives the rear spring to compress downwards. The back cover support legs are flush with the inclined surface of the protruding line head of the housing. The needle is rotated and slided downwards under the force of the rear spring until it is disengaged from the inclined surface and fired forward for blood sampling, while compressing the front spring.The needle will be retracted 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	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.	Similar (Note 1)

		relaxed rear spring and front spring. Therefore, the device cannot be re-used.		
Materials and composition	Safety lancet 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).	Safety lancet lancet is composed of spring, three-bevel edge needle or blade, housing, and slider.	The safety lancet are composed needle/ blade,silicone oil,spring and plastic part(back cover,slider,housing and protective cap).	Similar (Note 2)
Version	XA1 Pro, XA3 Pro, XA5 Pro,XA11 Pro	ZF1,ZF2, ZF1 Blade,ZF2 Blade	XY1,XY1 Blade, XH1,XH1 Blade, XA1	Different (Note 3)
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,Fall performance test, pH and total heavy metal	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,Fall performance test, pH and total heavy metal	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,Fall performance test, pH and total heavy metal	Same
Sterilization	Irradiation Sterilization SAL:10^{-6}	Irradiation Sterilization SAL:10^{-6}	Irradiation sterilized, SAL: 10^{-6}	Same
Labeling	Conform with 21 CFR 801	Conform with 21 CFR 801	Conform with 21 CFR 801	Same

Biocom-patibility	Meet the requirements of ISO10993 series standards, bocompatibility has been evaluated in K222090.	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	Single use	Same
Dimension/ gauge	18G,19G,20G,21G, 21G,22G,23G,24G, 25G,26G,27G,28G, 29G,30G,31G,32G, 33G(Needle type)	21G,22G,23G,24G,25G, 26G,27G,28G,29G, 30G (Needle type) 0.8mm,0.9mm,1.1mm, 1.2mm,1.5mm(Blade type)	Model XY: 21G,23G,25G,26G,28G,30G(Needle type), 1.2mm(Blade type) Model XH: 18G,21G,23G,28G (Needle type), 1.5mm (Blade type) Model XA: 21G,23G,28G(Needle type)	Different (Note 4)
Penetration depth	1.4mm/1.8mm/2.2mm, 1.6mm/2.0mm/2.4mm, 1.3mm/1.8mm/2.3mm, 1.5mm/2.0mm/2.5mm	1.2mm-2.8mm (Needle type) 1.8 mm-2.0mm (Blade type)	Model XY: 1.4mm-2.8mm(Needle type), 1.6mm-2.0mm (Blade type) Model XH: 1.2mm-2.8mm(Needle type),1.6mm-2.0mm(Blade type) Model XA: 1.3mm/1.8mm/2.3mm, 1.5mm/2.0mm/2.5mm(Needle type)	Different (Note 5)

Note 1:The design of the subject device is similar as the predicate device. Although the designs of the Model XA Pro, Model ZF and the predicate device have some differences, all models are used the elasticity of spring to launch a needle puncture for blood sampling. The performance of the subject device has been tested in the bench testing.Therefore,the difference will not affect the safety and effectiveness of the product.

Note 2:The materials and composition of the subject device are similar as the predicate device. For Model XA Pro, the materials and composition is same as the Model XA,except that the three indicator bars(indicated the penetration depth). The three indicator bars is on the knob of Model XA Pro(subject device), the three indicator bars is on the housing of Model XA(predicate device). The materials and composition of the predicate device has one more spring than Model ZF, the performance of the Model ZF has been tested in the bench testing.Therefore,the difference will not affect the safety and effectiveness of the product.

Note 3:The version of the subject device is different as the predicate device. The version is named as the different penetration depth, different needle type/blade type and material of slider. The version do no affect the safety and effectiveness of the product.

Note 4:Model XA Pro only has needle type, Model ZF has needle type and blade type. The subject device has needle type and blade type. The dimension/gauge of Model XA Pro is 18G-33G, the predicate device is not including 19G/20G/22G/24G/27G/29G/31G/32G/33G. The dimension/gauge of Model ZF is 21G-30G(Needle type) and 0.8mm,0.9mm,1.1mm, 1.2mm,1.5mm(Blade type), the predicate device is not including 22G/24G/27G/29G(Needle type) and 0.8mm,0.9mm,1.1mm(Blade type).The needle gauge of subject device is a widely used in the market and meet the requirements ISO 9626:2016, the different blade width of subject device is smaller than the predicate device. The dimension/gauge of the subject device also has been tested in the bench testing.Therefore,the difference will not affect the safety and effectiveness of the product.

Note 5: Model XA Pro has four versions, which have three penetration depths for depth setting ,the range of penetration depth is 1.3mm-2.5mm. The penetration depth range of Model XA(subject device) is 1.3mm-2.5mm. Therefore, their extreme depth is the same. The penetration depth of Model ZF is 1.2mm-2.8mm(Needle type) and 1.8 mm-2.0mm (Blade type), the penetration depth range of the predicate device is 1.2mm-2.8mm(Needle type) and 1.6mm-2.0mm(Blade type). The range of penetration depth for the blade type subject device is getting shorter than the predicate device.It means the the length of puncture entering the skin is not longer, which will not increase 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.

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

Items	Requirements	Results
Dimension	Dimension should meet the requirements.	Passed
Appearance	The needle holder should be smooth and free of defects such as burrs, oil stains, rust spots, and bending. The housing should be smooth, free of burrs, bubbles, impurities and cracks. With normal or corrected to normal vision, there should be no visible accumulation of lubricant on the outer surface of the needle tip.	Passed
Needle-tip	The tip of the lancet should have no flat head, burrs and hooks.Penetration Force should meet the requirements.	Passed
Trigger force	The lancet should be activated against 2N～20N axial pressure.	Passed
Corrosion resistance feature	Needle should have good corrosion resistance feature.	Passed
Retractable	After use, the needle can be automatically retracted.	Passed
Penetration Depth	Penetration depth should meet the requirements.	Passed
Challenge Safe Mode-Resistance	Apply a 15N force horizontally at the raised platform of the lancet, and the back cover must not be detached.	Passed
Challenge Safe Mode-Needle Tip Exposed	After the needle tip of the lancet is retracted, the needle tip cannot be exposed. Observe the needle tip after removing the protective cap, the needle tip should not be exposed.	Passed
Anti-activation test	The lancet should not activate when it is mistakenly pushed the button before use.	Passed

Self-destruct performance test	The lancet should not be activated again after use.	Passed
Fall Performance	The product falls freely to a smooth hard surface at a height of 1 meter, than test the appearance,triggering force,retraction and penetration depth should meet the requirements.	Passed
pH and total heavy metal content and Cd content	pH(difference of blank solution)≤1,Total heavy metal content≤5mg/L and Cd content ≤0.1mg/L	Passed
Sterility	After the safety lancet has been sterilized by radiation, the needle tip should be sterile.	Passed

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.

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.

Select the most widely sold in the market of each model as typical product for study.The results show that the product has well sharps injury prevention feature.

9.Conclusions

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