9/30/2022

Ningbo Medsun Medical Co., Ltd.
Liu Ping
Regulation Affairs Manager
No.55 Jinxi Road, Zhenhai
Ningbo, Zhejiang 315221
China

Re: K222090/S001
Trade/Device Name: Safety Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood lancets
Regulatory Class: Class II
Product Code: FMK
Dated: July 11, 2022
Received: July 15, 2022

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 (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)*
K222090

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: July 11th, 2022

2.Submitter

Ningbo Medsun Medical Co., Ltd.

No.55 Jinxi Road, Zhenhai, 315221, Ningbo, P.R.China

Contact Person: Liu Ping, Regulation Affairs Manager

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Primary correspondent: Marvin Li, Consultant

Tel:+86-15257179656 E-mail: leeking0908@126.com

Date Prepared: July 11th, 2022

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 8780.4850

Regulatory Class: II

Product Code: FMK

Review Panel: General & Plastic Surgery

4.Predicate device

4.1Predicate device A

Manufacturer: Promisemed Hangzhou Meditech Co., Ltd.

Device name: VeriFine Safety Lancet

510(k) number: K192666

4.2Predicate device B

Manufacturer: Medipurpose Pte Ltd.

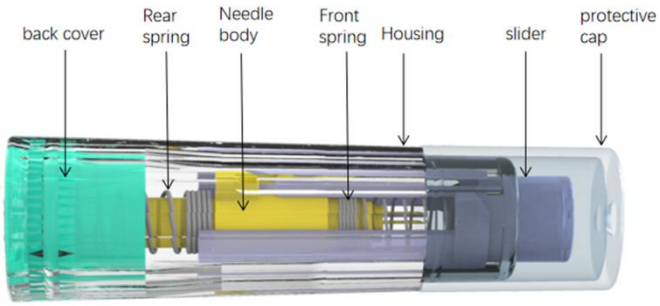
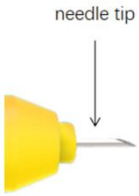
Device name: Surgilance® Safety Lancets

510(k) number: K101145

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)

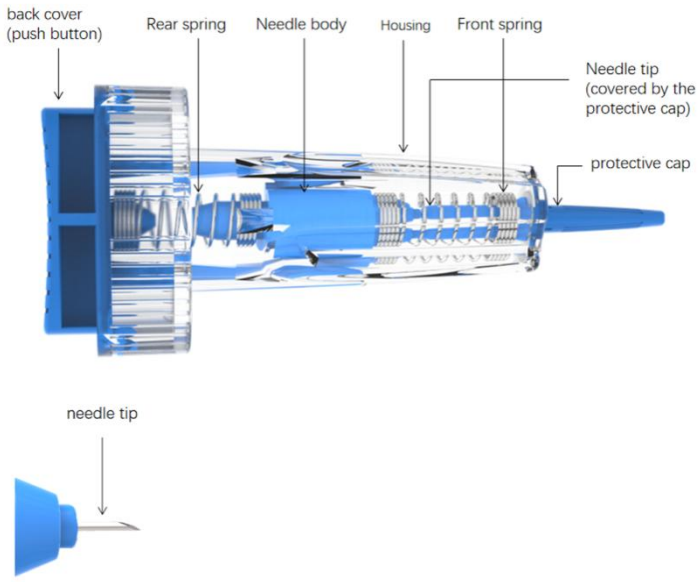
Design features:

- 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

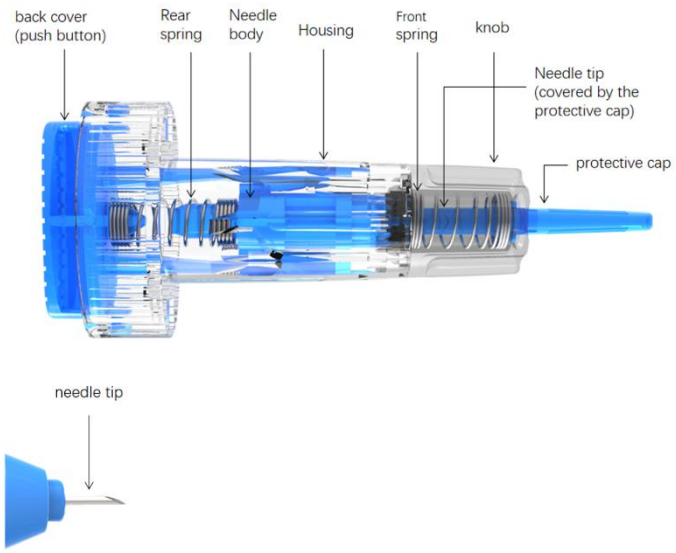
Model XH is composed of a protective cap, a front spring, housing, needle body with tri-bevel edge needle or blade, a rear spring and a back cover (push button). The needle body with needle or blade is hidden inside the housing/protective cap. The device is colour coded for different versions.

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 other testing where capillary blood is required.

7.Comparison of technological characteristics with the predicate device

Description	Subject Device	Predicate Devices A (K192666)	Predicate Devices B (K101145)	Remark
Product Code	FMK	FMK	FMK	Same
Regulation Number	21CFR 8780.4850	21 CFR 878.4800	21 CFR 878.4800	Different
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.	It is intended for capillary blood sampling.	The SurgiLance® Safety Lancet is a puncture device to obtain micro blood samples. The SurgiLance® Safety Lancet has a sharp's prevention feature to protect the user from a needlestick injury.	Same (Note 1)
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. When the slider is pressed, the slider pushes the two bosses of the needle holder backwards. The bosses move	These lancets are precision sharpened designed for maximum comfort and optimal blood flow. Safety lancets are designed to make taking a blood sample simple and easy. Safety lancets are activated when	The Surgilance® Safety Lancet is safely retracted and concealed before and after use.The user simply removes the protective cap , places the red raised platform end onto the patient's test site , and gently push the lancet	Similar (Note 2)

	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.	you press the device against your finger. Once activated the needle retracts into the body of the device which reduces the risk of injury as the result if an exposed needle. The first spring releases the needle into the skin and the second withdraws the needle back into the shield.	down against the test site to activate the lancet mechanism . Once the lancet is used , it is rendered inoperative , providing added safety for patient and clinician . The device is discarded in a sharps container after use	
Materials	The safety lancet are composed needle/blade,Silicone oil,spring and plastic part(back cover,slider,housing and protective cap).	The needles all use medical grade stainless steel and the rest part(plastics for the Shield, hub, caps, and triggers) are made of plastics materials.	The needles and blades all use medical grade stainless steel and the housings are made of plastics. The housings, caps, and triggers are made of plastics materials.	Same (Note 3)
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.	VeriFine Safety Lancet offers different gauge (needle diameter) options, to allow to choose the lancet which meets blood volume needs.	The SurgiLance® Safety Lancet comes in six models: two low flow, one medium flow, one medium-high flow, and two high flows. The six models are differentiated by their casing color.	Similar (Note 4)

Performance	Dimension,Appearance,Needle-tip,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	Visual Inspection, Needle Dimensions, Chemical properties, Bond between lancet body and needle, Resistance to corrosion of the needle,Locking function,Spring elasticity,Percussive function,Penetrate force	/	Same as Predicate Devices A
Sterilization	Irradiation Sterilization SAL:10^{-6}	Irradiation sterilized, SAL: 10^{-6}	/	Same as Predicate Devices A
Labeling	Conform with 21 CFR 801	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.	Conform with ISO 10993 standards, Cytotoxicity, Sensitization, Irritation, were performed to demonstrate Biocompatibility.	/	Similar (Note 5)
Reuse or single use	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)	Gauge: 18G,21G,23G,25G, 26G,28G,30G Penetration depth: 1.2mm, 1.4mm, 1.6mm, 1.8mm, 2.0mm, 2.2mm, 2.4mm, 2.6mm, 2.8mm	Needle type: 21G, 1.0mm 21G, 1.8mm 21G, 2.2mm 21G, 2.8mm Blade type: 18G, 1.8mm 18G, 2.3mm	Similar (Note 6)
	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)			
	Model XA Dimension/gauge: 21G,23G,28G (Needle type) Penetration depth: 1.3mm/1.8mm/2.3mm,1.5mm/2.0mm/2.5mm(Needle type)			

Note 1:The indications for use statements are not identical in wording, however, demonstrate the same desired intended use. Both devices are intended for use for obtaining blood samples. The overarching principal nature of the lancing devices is to obtain blood samples. Both the predicates and subject device have this goal as the main aspect of the indication for use statement. It is also important to note both the subject device and predicate B state the inclusion of a sharps safety prevention feature into the product design.

Note 2: Model XY has the same design with predicate device A and B, lancet is activated when press the device's slider against the body site. Model XH and Model XA have the different feature is that lancet is activated when press the device's push button(back cover). Although there are slight differences in design, they all use the elasticity of springs and the structure of plastic parts to realize their functions. All of the models have been testing for the safety and effectiveness.

Note 3: The subject device and predicate device B all have needle/blade type, but the predicate device A only has needle type. Predicate device B has marketed for many years, it indicates that the blade type is safe and effective.

Note 4: All the devices have different models, only there are some differences in the way of distinguishing models. Besides, subject device has three model:Model XY,Model XH and Model XA. They are have different appearance, the needle body with needle or blade is hidden inside the housing/slider of Model XY, the needle body with needle or blade is hidden inside the housing/protective cap of Model XH and Model XA. The Model XA can adjustable the penetration depth, and the Model XY and Model XH can not adjustable the penetration depth.

Note 5: The predicate device A was tested Cytotoxicity, Sensitization and Irritation to demonstrate biocompatibility. The subject device was tested In vitro cytotoxicity, skin sensitization,intracutaneous reactivity, acute systemic toxicity and pyrogen to demonstrate biocompatibility. The test content of the subject devices is more strict than the predicate device A.

Note 6: The needle of subject device and predicate device B have two types, needle type and blade type. The needle of predicate device A only has needle type .The needles are all solid cylindrical needles.The difference of the needle is that needle type is tri-bevel edge needle tip and blade type is two-bevel edge needle tip. Dimension/gauge of the needles all meet the requirements ISO 9626:2016. Therefore, the 1.2mm blade type needle of subject device is equal to 18G, 1.5mm blade type needle of subject device is equal to 17G. The subject device has 18G(1.2mm),21G,23G,25G,26G,28G,30G needle, which is same as the predicate device A, excpet 17G(1.5mm). According to ISO 9626:2016, the most thickest needle reaches to 10G, so the 17G(1.5mm) needle can be used clinically. Additional, the 17G(1.5mm) needle of the subject device havs been marketed on EU market and no adverse event was collected. The subject device and predicate device A/B all have different penetration depth.But the range of the subject device’s penetration depth is from 1.2mm to 2.8mm, which is the same as the penetration depth of predicate device A(1.2mm-2.8mm).

8.Performance testing summary

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

8.1Biocompatibility testing

Per FDA Guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”, issued on September 4, 2020. The biocompatibility evaluation items of proposed device were completed for each model and each sterilization method(Co-60 and e-beam) individually. The testing included the following tests:

- In vitro cytotoxicity
- Skin sensitization
- Intracutaneous reactivity
- Acute systemic toxicity
- Pyrogen

8.2Performance testing-Bench

Safety Lancet with different sterilization method(Co-60 and e-beam) had been tested individually.The test items mainly include the following contents.

- Dimension
- Appearance
- Needle-tip
- Trigger force
- Corrosion resistance feature
- Retractable
- Penetration Depth
- Challenge Safe Mode- Resistance
- Challenge Safe Mode- Needle Tip Exposed
- Anti-activation test(only for Model XH and XA)
- Self-destruct performance test
- Sterility
- pH and total heavy metal content and Cd content
- Bacterial Endotoxins

Beside, 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 for each model. The test results show that the product had 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 (K192666, K101145).