June 26, 2025

Tianjin Huahong Technology Co., Ltd.
Ningning Wang
Registered Engineer
A01, Plant B, No. 278 Hangkong Road
Tianjin Pilot Free Trade Zone (Air Port Industrial Park)
Tianjin, 300308
China

Re: K251694
Trade/Device Name: safety lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: June 1, 2025
Received: June 2, 2025

Dear Ningning Wang:

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,

James H. Jang -S
Digitally signed by James H. Jang -S
Date: 2025.06.26 07:31:57 -04'00'

James Jang, 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.	K251694

Please provide the device trade name(s).

safety lancet

Please provide your Indications for Use below.

The safety lancet is intended for capillary blood sampling.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) summary

I Submitter

Tianjin Huahong Technology Co., Ltd.
A01, Plant B, No.278, Hangkong Road, Tianjin Pilot Free Trade Zone (Air Port Industrial Park), 300308 Tianjin, China

Establishment Registration Number: 3009498536

Contact person: Ms. Ningning Wang
Registered Engineer
Tel.: +86-13021381776
E-mail: ningning.wang@hh-technology.com

Preparation date: 1 June 2025

II Proposed Device

Trade Name of Device:	Safety Lancet (XXXVI)
Common name:	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature
Regulation Number:	21 CFR 878.4850
Regulatory Class:	Class II
Product code:	FMK
Review Panel	General & Plastic Surgery

III Predicate Devices

510(k)Number:	K240806
Trade name:	Safety Lancet
Classification:	Class II
Product Code:	FMK
Manufacturer	Tianjin Huahong Technology Co., Ltd.

IV Device description

The safety lancet is single use medical device, which is designed to collect capillary blood sample.

The intended users include Healthcare personnel, patients and lay persons.

Model XXXVI, the safety lancets consist of needle core, button, housing, protective cap and spring.

The sterile part of the safety lancet is the needle tip.

The sterile barrier is the needle sleeve and sterilized to a SAL of 10^{-6} by radiation sterilization.

It is intended for single use only. The shelf-life of the product is 5 years.

V Indication for use

The safety lancet is intended forcapillary blood sampling.

VI Comparison of technological characteristics with the predicate devices

The comparison and discussion between the subject device and the predicate device are listed in below table 1:

Table 1 General Comparison of Safety Lancet

Item	Predicate device (K240806)	Proposed device	Comments on Similarities/Differences	Safety/Effectiveness Statement
Product name	Safety Lancet	No Change	N/A	No new concerns. The product name remains unchanged
Product Code	FMK	No Change	N/A	No new concerns. The product code remains the same, reflecting no change in device functionality.
Regulation No.	21 CFR § 878.4850	No Change	N/A	No new concerns. The regulation number remains consistent.
Class	II	No Change	N/A	No new concerns. The device remains in Class II, indicating no change in risk level.
Prescription/over-the-counter use	Over-The-Counter Use	No Change	N/A	No new concerns. The over-the-counter use remains consistent.
Indication for use	The safety lancet is intended for capillary blood sampling.	No Change	N/A	No new concerns. The Indication for use remains consistent.
Applicable user	Healthcare professional or lay person	No Change	N/A	No new concerns. The applicable user remains consistent.

Reuse durability	Single use	No Change	N/A	No new concerns. The single use remains consistent.
Sterilization method and SAL	Sterilized by Radiation SAL=10^{-6}	No Change	N/A	No new concerns. The sterilization method and SAL remains consistent.
Manufacturing aspects	The injection molding of the needle core is completed in the purification workshop, the steel needle is wrapped in the needle core, sterilization of the needle core is outsourced, the subsequent process is the assembly and packaging of the safety lancet	No Change	N/A	No new concerns. The manufacturing aspects remains consistent.
Design and Functionality aspects	The needle tip is sterile, and the plastic part of the needle core serves as a sterile barrier for the needle tip. When using, the cap needs to be twisted off first, after pressing the button, the safety needle is activated, and the needle tip penetrates the skin under the action of the spring, Subsequently, under the action of the spring, the needle tip retracts back into the safety needle.	No Change	N/A	No new concerns. The design and functionality aspects remains consistent.
Gauge range	1.50±0.02mm（16G） 1.40±0.02mm（17G） 1.20±0.01mm（18G） 1.07±0.01mm（19G）	No Change	N/A	No new concerns. The gauge range remains consistent.

	0.91±0.01mm（20G） 0.82±0.01mm（21G） 0.72±0.01mm（22G） 0.64±0.01mm（23G） 0.57±0.01mm（24G） 0.51±0.01mm（25G） 0.46±0.01mm（26G） 0.41±0.01mm（27G） 0.36±0.01mm（28G） 0.34±0.01mm（29G） 0.31±0.01mm（30G） 0.26±0.01mm（31G） 0.24±0.01mm（32G） 0.21±0.01mm（33G） 0.19±0.01mm（34G） 0.18±0.01mm（35G） 0.17±0.01mm（36G） 0.16±0.01mm（37G） 0.15±0.01mm（38G）			
Shelf-life	5 years	No Change	N/A	No new concerns. The shelf-life remains consistent.
Materials of parts in contact with human body	Needle: stainless steel, silicone oil Housing, Button: ABS, PS, PP	Needle: stainless steel, silicone oil	added the protective cap	No new concerns. Just added the protective cap, no change in material.

	and Calcium powder	Housing, Button, Protective cap: ABS, PS, PP and Calcium powder		
Biocompatibility	Conforms to the requirements of ISO 10993 series standards.	No Change	N/A	No new concerns. The biocompatibility remains consistent.
Performance requirements	Remain no change	No Change	N/A	No new concerns. Performance requirements remain unchanged, ensuring consistent functionality.
Label/Labeling	Complied with 21 CFR part 801	No Change	N/A	No new concerns. The labeling remains consistent.

VII Non-Clinical Testing
To support substantial equivalence to the predicate device, Tianjin Huahong Technology Co., Ltd. completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met.

Verification and Validation Activities - Design Changes:
Model: Additional model were introduced to meet clinical needs, Model XXXVI have only cosmetic and dimensional changes from those in K240806.

Testing Performed:
Performance Testing: The safety lancet underwent performance testing (report HH-JS-RP-2024-10), The testing confirmed that the safety lancet meet the performance criteria outlined.

Biocompatibility Testing:

The biocompatibility evaluations were conducted in accordance with the 2023 FDA Guidance document Use of International Standard ISO 10993-1 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process”. The tests include the following tests:

The formulation, processing, sterilization, geometry in the previously approved safety lancet products (K220370) are the same, and the nature and duration of contact with the patient are also the same.

Item	Test method	Test results
In Vitro Cytotoxicity	ISO 10993-5: 2009	No Cytotoxicity
Skin Sensitization	ISO 10993-10: 2010	No Skin sensitization
Intracutaneous reactivity	ISO 10993-10: 2010	No irritation
Acute Systemic Toxicity	ISO 10993-11: 2017	No Acute SystemicToxicity
Pyrogenicity	ISO 10993-11: 2017	no thermogenic reaction

Simulated Clinical Use
A simulated clinical use study was performed on 500 device samples each for the safety lancet according to FDA Guidance, Guidance for Industry and FDA Staff: Medical Device with Sharps Injury Prevention Feature, issued on August 9, 2005 and ISO 23908 to evaluate the safety mechanism of the proposed device. The results demonstrated that the proposed device met the pre-established criteria.

Test Results:
All verification and validation tests passed without deviations, confirming that the safety lancet meet the necessary design specifications and regulatory requirements. The tests demonstrated that the product modifications did not introduce any new risks related to safety or effectiveness when compared to the predicate device.

Conclusions:

Based on the results of the non-clinical verification and validation activities, it can be concluded that the modified safety lancet are substantially equivalent to the predicate device K240806. The cosmetic and dimensional changes, have been thoroughly evaluated and verified to meet all applicable performance and safety standards. Therefore, the device is as safe and effective as the predicate device for its intended use, and no new risks have been introduced.

VIII Clinical Testing

No clinical study is included in this submission.

IX Conclusion

Any minor differences in the technological characteristics of the proposed device, when compared to the predicate devices have been successfully evaluated through appropriate safety and performance testing which demonstrates that the proposed device, when compared to the predicate device, does not raise any new questions of safety and effectiveness. Therefore, the proposed device have been determined to be substantially equivalent to the predicate devices.