March 31, 2026

Tianjin Huahong Technology Co., Ltd.
Ningning Wang
Registered Engineer
Contact Address

Re: K260191
Trade/Device Name: Safety lancet (XXXVII)
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: February 5, 2026
Received: January 22, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

JAMES H. JANG -S

Digitally signed by JAMES H. JANG -S
Date: 2026.03.31 22:39:25 -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.	K260191

Please provide the device trade name(s).

Safety lancet (XXXVII)

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

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
- ☐ Infants (29 days old to < 2 years old)
- ☐ Children (2 years old to < 12 years old)
- ☐ Adolescents (12 years old to < 22 years old)
- ☐ Adults (22 years old and greater)

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: February 4, 2026

II Proposed Device

Trade Name of Device:	Safety Lancet (XXXVII)
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 XXXVII, the safety lancets consist of needle core, button, housing, ring 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 proposed device and the predicate device are listed in below table 1:

Table 1 General Comparison of Safety Lancet

Item	Predicate device (K240806)	Proposed device (K260191)	Comments
Product name	Safety Lancet	Safety Lancet	Same
Product Code	FMK	FMK	Same
Regulation No.	21 CFR § 878.4850	21 CFR § 878.4850	Same
Class	II	II	Same
Prescription/over-the-counter use	Over-The-Counter Use	Over-The-Counter Use	Same
Indication for use	The safety lancet is intended for capillary blood sampling.	The safety lancet is intended for capillary blood sampling.	Same
Applicable user	Healthcare professional or lay person	Healthcare professional or lay person	Same
Reuse durability	Single use	Single use	Same
Sterilization method and SAL	Sterilized by Radiation SAL=10^{-6}	Sterilized by Radiation SAL=10^{-6}	Same
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	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	Same
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. Set the penetration depth	The needle tip is sterile, and the plastic part of the needle core serves as a sterile barrier for the needle tip. Set the penetration depth by turning the depth adjuster ring before use.	Different 1

	by turning the depth adjuster ring before use. 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.	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 **retract spring**, the needle tip retracts back into the safety needle.	
Gauge range	1.50±0.02mm（16G） 1.40±0.02mm（17G） 1.20±0.01mm（18G） 1.07±0.01mm（19G） 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）	1.50±0.02mm（16G） 1.40±0.02mm（17G） 1.20±0.01mm（18G） 1.07±0.01mm（19G） 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）	Same

	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）	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	5 years	
Materials of parts in contact with human body	Needle: stainless steel, silicone oil Housing, Button, Ring: ABS, PS, PP and Calcium powder	Needle: stainless steel, silicone oil Housing, Button, Ring: ABS, PS, PP and Calcium powder	Same
Biocompatibility	All materials are identical to those of the predicate device and have been evaluated in accordance with ISO 10993 series standards	All materials are identical to those of the predicate device and have been evaluated in accordance with ISO 10993 series standards	Same
Performance requirements	Performance requirements are unchanged, and verification testing confirms that the proposed device meets the same performance specifications as the predicate device	Performance requirements are unchanged, and verification testing confirms that the proposed device meets the same performance specifications as the predicate device	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Different 1 – Internal Spring Mechanism The proposed device (Model XXXVII) and the predicate device (Model XXIX, K240806) have the same intended use, user interface, operating steps, and fundamental operating principle. For both devices, the user removes the cap, sets the penetration depth using the depth adjustment			

ring, and activates the device by pressing the button, resulting in needle penetration followed by automatic retraction of the needle into the housing.

The proposed device utilizes an internal dual-spring configuration to achieve needle activation and retraction, whereas the predicate device utilizes a single-spring configuration. Despite this difference in internal spring configuration, the functional outcome and performance characteristics of the two devices remain the same.

The dual-spring configuration in the proposed device does not affect penetration depth, activation force, needle retraction function, or overall device performance. Non-clinical verification and validation activities, including functional and performance testing, demonstrated that the proposed device performs equivalently to the predicate device. This difference in internal design does not raise new questions of safety or effectiveness.

VII Non-Clinical Testing

Non-clinical verification and validation testing was conducted to support a determination of substantial equivalence for the proposed Safety Lancet (Model XXXVII).

The non-clinical testing program was designed to evaluate the safety and performance of the proposed device and to demonstrate that it performs as intended when compared to the legally marketed predicate device (K240806). Testing addressed the device's functional performance, safety mechanism reliability, material biocompatibility, and sterility assurance.

Performance Testing:

Performance testing was conducted to evaluate critical functional characteristics of the Safety Lancet, including device activation, needle penetration, automatic needle retraction, and overall functional reliability (Test Report No. HH-JS-RP-002-2025-11).

All tested samples met the predefined acceptance criteria, and the results demonstrated that the proposed device performs equivalently to the predicate device.

Biocompatibility Testing:

Biocompatibility evaluation was performed in accordance with FDA Guidance *Use of International Standard ISO 10993-1: Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process*.

All patient-contacting materials, manufacturing processes, sterilization method, geometry, and the nature and duration of contact are identical to those of the legally marketed predicate device. The following tests were completed:

- In Vitro Cytotoxicity (ISO 10993-5): No cytotoxicity
- Skin Sensitization (ISO 10993-10): No sensitization
- Intracutaneous Reactivity (ISO 10993-10): No irritation
- Acute Systemic Toxicity (ISO 10993-11): No toxicity
- Pyrogenicity (ISO 10993-11): No thermogenic response

Simulated Clinical Use Testing

A simulated clinical use study was conducted using 300 samples of the proposed Safety Lancet in accordance with FDA Guidance Medical Devices with Sharps Injury Prevention Features (August 9, 2005) and ISO 23908.

The study evaluated the effectiveness and reliability of the sharps injury prevention mechanism under simulated use conditions, including needle activation and automatic retraction. All tested devices met the pre-established acceptance criteria, and no failures were observed.

Summary of Non-Clinical Test Results:

The results of non-clinical testing demonstrate that the proposed Safety Lancet meets its design and performance specifications and is as safe and effective as the predicate device.

VIII Clinical Testing

Clinical performance data were not required to support a determination of substantial equivalence for the proposed Safety Lancet. Substantial equivalence was adequately demonstrated through non-clinical performance testing, biocompatibility evaluation, and simulated clinical use testing.

IX Conclusion

Based on a comparison of intended use, technological characteristics, and performance, as well as the results of non-clinical verification and validation testing, the proposed Safety Lancet (Model XXXVII) is substantially equivalent to the legally marketed predicate device (K240806). The proposed device does not raise any new questions of safety or effectiveness.