February 12, 2026

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: K252490
Trade/Device Name: Heel Stick Safety Lancet (HHZ-II, HHZ-III, HHZ-IV)
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood lancets
Regulatory Class: Class II
Product Code: FMK
Dated: August 8, 2025
Received: January 16, 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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.02.12 21:19:18 -05'00'

Colin Kejing Chen, 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
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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.*

510(k) Number *(if known)*
K252490

Device Name
Heel Stick Safety Lancet (HHZ-II, HHZ-III, HHZ-IV)

Indications for Use *(Describe)*
Heel Stick Safety Lancet is intended for the collection of capillary blood from the heel of newborn, preemie, and toddler. The lancet has equipped with safety protection features.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) summary

## I Submitter

Tianjin Huahong Technology Co., Ltd.
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Establishment Registration Number: 3009498536

Contact person: Ms. Ningning Wang
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E-mail: ningning.wang@hh-technology.com

Preparation date: August 8, 2025

## II Proposed Device

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|---|---|
| Trade Name of Device: | Heel Stick Safety Lancet |
| 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: | K220372 |
| Trade name: | Heel Stick Safety Lancet |
| Classification: | Class II |
| Product Code: | FMK |
| Manufacturer | Tianjin Huahong Technology Co., Ltd. |

## IV Device description

The heel stick safety lancet is offered in various depth size (0.65mm, 0.85mm, 1.00mm, 1.50mm,1.8mm) and width size (1.50 mm, 1.75mm, 2.50 mm, 2.80 mm, 3.0 mm).
It consists of blade base, blade, which is welded with the blade base, spring, top head, bottom, and pushing button. The top head and bottom are intended to provide physical protection to the blade, and PET blister along with the tyvek paper cover the primary sterile barrier system for the device. The product is individually primarily packaged 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.
Heel stick safety lancet is intended to be used by professionals. The product is intended for prescription (Rx) only.

## V Indication for use

Heel stick safety lancet is intended for the collection of capillary blood from the heel of newborn, preemie, and toddler. The lancet has equipped with safety protection features.

## VI Comparison of technological characteristics with the predicate devices

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

Table 1 General Comparison

| Item | Predicate device (K220372) | Proposed device | Comments on Similarities/Differences | Safety/Effectiveness Statement |
|---|---|---|---|---|
| Product name | Heel Stick Safety Lancet | No Change | N/A | No new concerns.<br>The product name remains unchanged |
| Product Code | FMK | No Change | N/A | No new concerns.<br>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.<br>The regulation number remains consistent. |
| Class | II | No Change | N/A | No new concerns.<br>The device remains in Class II, indicating no change in risk level. |
| Prescription/over-the-counter use | prescription (Rx) only | No Change | N/A | No new concerns.<br>The prescription (Rx) only remains consistent. |
| Indication for use | Heel stick safety lancet is intended for the collection of capillary blood from the heel of newborn, preemie, and toddler. The lancet has equipped with safety protection features. | No Change | N/A | No new concerns.<br>The Indication for use remains consistent. |
| Applicable user | Healthcare professional | No Change | N/A | No new concerns. |

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| | | | | The applicable user remains consistent. |
| Reuse durability | Single use | No Change | N/A | No new concerns.<br>The single use remains consistent. |
| Sterilization method and SAL | Sterilized by Radiation<br>SAL equal or less than $10^{-6}$ | No Change | N/A | No new concerns.<br>The sterilization method and SAL remains consistent. |
| Manufacturing aspects | The heel blood collection device is composed of a blade spring and plastic components (cover, base, blade holder, buttons). It is assembled through assembly. The finished product is sealed with PET film and tyvek paper to form a sterile barrier system, protecting the heel blood collection device and preventing it from getting contaminated.The injection molding, assembly and initial packaging processes are carried out in the cleanroom, while sterilization is outsourced. | No Change | N/A | No new concerns.<br>The manufacturing aspects remains consistent. |
| Design and Functionality aspects | The sterile barrier system protecting the heel blood collection device is sterile. When using it, the product needs to be removed first (HHZ IV need to remove the self-locking splinter), and then by pressing the button, the heel blood collection device will be activated. The blade will penetrate the skin under the action of the spring. | No Change | N/A | No new concerns.<br>The design and functionality aspects remains consistent. |

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| | Subsequently, under the action of the spring, the blade will retract back into the product. | | | |
| Model | HHZ-II<br>HHZ-III | HHZ-II<br>HHZ-III<br>HHZ-IV | Increase model | No new concerns.<br>The HHZ-IV adds a self-locking splinter. This is a safety enhancement designed to prevent false triggering and reduce the existing risk of accidental activation. Its operation is intuitive and does not introduce new material contacts, risks, failure modes, or operational complexity. Its core functionality, performance, intended use, and overall safety and effectiveness characteristics are essentially equivalent to those of the HHZ-II/HHZ-III, with improved safety by reducing the probability of false triggering. This has been confirmed through |

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| | | | | design verification and updated risk analysis. |
| Specification | 0.65mm*1.50mm<br>0.85mm*1.75mm<br>1.00mm*2.50mm<br>1.50mm*2.80mm | 0.65mm*1.50mm<br>0.85mm*1.75mm<br>1.00mm*2.50mm<br>1.50mm*2.80mm<br>1.80mm*3.00mm | Increase specifications | No new concerns.<br>Verification testing has been conducted on the performance characteristics of the newly added specifications using the same test methods and acceptance criteria as the original licensed specifications. The test results fully demonstrate that the newly added specifications meet all applicable performance and safety standards and confirm their performance equivalence. |
| Shelf-life | 5 years | No Change | N/A | No new concerns.<br>The shelf-life remains consistent. |
| Materials of parts in contact with human body | Stainless steel, ABS | No Change | N/A | No new concerns.<br>The Materials remains consistent. |
| Biocompatibility | Conforms to the requirements of ISO 10993 series standards. | No Change | N/A | No new concerns. |

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| | | | | 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.<br>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:**

This change includes two items:

(1) A new model HHZ-IV is added, which adds a self-locking splinter based on HHZ-II/HHZ-III to reduce the risk of "false triggering".

(2) A new specification of 1.80mm x 3.00mm is added, which is an extension of the existing specification.

A comprehensive evaluation (including design verification, risk analysis update, and performance testing) confirmed that:

This self-locking splinter is only a safety enhancement design. The design is intuitive and easy to operate. It does not introduce new material contacts, new hazards or operational complexity, and significantly reduces the probability of false triggering. The design, materials, and processes of the new specifications are consistent with the existing specifications. Engineering analysis and testing have proven that it will not change the core performance parameters of the device. These performance parameters have been confirmed to meet the standards of the original license (K220372) through equivalence verification or supplementary testing. The technical characteristics, intended use, safety and effectiveness characteristics of the device are substantially equivalent to those of the original license (K220372), and safety is improved by reducing the risk of false triggering. There is no negative impact on the effectiveness of the product or the introduction of new risks.

**Testing Performed:**

Performance Testing: The heel stick safety lancet underwent performance testing (report HH-JS-RP-2024-06), 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 heel stick safety lancet products (K220372) 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 heel stick 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 heel stick safety lancet is substantially equivalent to the predicate device K220372. The 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.