Tianjin Huahong Technology Co., Ltd.
Ningning Wang
Registered Engineer
A01, Plant B, # 278, Hangkong Rd.
Tianjin Pilot Free Trade Zone(Air Port Industrial Park)
Tianjin, 300308
China

December 9, 2025

Re: K253706
Trade/Device Name: Lancing device (HH-XV-T)
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL
Dated: November 24, 2025
Received: November 24, 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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.12.09 14:32:12 -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
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.

510(k) Number *(if known)*
K253706

Device Name
Lancing device (Model: HH-XV-T)

Indications for Use *(Describe)*
Without Clear Cap configuration: The Lancing Device is used with lancets to draw capillary blood from the fingertip, for testing utilizing small amounts of blood. The Lancing Device is intended to be used by a single patient and should not be shared.
With Clear Cap configuration: The Lancing Device is used with lancets to draw capillary blood from the fingertip, palm (at the base of the thumb) or forearm, for testing utilizing small amounts of blood. The Lancing Device is intended to be used by a single patient and should not be shared.

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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PRAStaff@fda.hhs.gov

"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.
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: November 24, 2025

II Proposed Device

Trade Name of Device:	Lancing device
Common name:	Multiple Use Blood Lancet For Single Patient Use Only
Regulation Number:	21 CFR 878.4850
Regulatory Class:	Class II
Product code:	QRL
Review Panel	General & Plastic Surgery

III Predicate Devices

510(k) Number:	K243306
Trade name:	Lancet, Lancing device
Classification:	Class II
Product Code:	QRL, QRK
Manufacturer:	Tianjin Huahong Technology Co., Ltd.

IV Device description

Model: HH-XV-T

Along with a lancet, the lancing device is used to obtain a capillary blood sample. The body and the active parts of the lancing device are made of ABS, POM, PC and PS. And the spring is made of carbon steel.

The device is available in two configurations:

- **Without clear cap**: Fingertip use only
- **With clear cap**: Fingertip, palm (base of thumb), and forearm

The device is provided non-sterile and is intended for single-patient reuse, with a service life of no less than 3000 times.

V Indication for use

Without Clear cap configuration:

The Lancing Device is used with lancets to draw capillary blood from the **fingertip**, for testing utilizing small amounts of blood. The Lancing Device is intended to be used by a single patient and should not be shared.

With Clear cap configuration:

The Lancing Device is used with lancets to draw capillary blood from the **fingertip, palm (at the base of the thumb) or forearm**, for testing utilizing small amounts of blood. The Lancing Device is intended to be used by a single patient and should not be shared.

Summary of Modification:

This Special 510(k) includes an **expanded Indication for Use** for model HH-XV-T (addition of palm and forearm) and an **additional disinfection method** (Discide® Ultra Disinfecting Wipes).

VI Comparison of technological characteristics with the predicate devices

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

Table 1 Substantial Equivalence Comparison

Item	**Predicate device** **Model: HH-XXVII-T** **Model: HH-XV-T** **(K243306)**	**Proposed device** **Model: HH-XV-T** **（K253706）**	**Comments**
Product name	Lancing device	Lancing device	Same
Product Code	QRL	QRL	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	Model HH-XV-T: The Lancing Device is used with lancets to draw capillary blood from the fingertip, for testing utilizing small amounts of blood. The Lancing Device is intended to be used by a single patient and should not be shared. Model HH-XXVII-T：The Lancing Device is used with lancets to draw capillary blood from the fingertip, palm (at the base of the thumb) or forearm, for testing utilizing small amounts of blood. The Lancing Device is intended to be	Without Clear Cap configuration: The Lancing Device is used with lancets to draw capillary blood from the fingertip, for testing utilizing small amounts of blood. The Lancing Device is intended to be used by a single patient and should not be shared. With Clear Cap configuration: The Lancing Device is used with lancets to draw capillary blood from the fingertip, palm (at the base of the thumb) or forearm, for testing utilizing small amounts of blood. The Lancing Device is intended to be used by a single patient and should not be shared.	Same

		used by a single patient and should not be shared.		
Puncture device to obtain micro blood samples		Yes	Yes	Same
Lancet retracted after use to prevent sharp injure		Yes	Yes	Same
Materials		ABS, POM, PC and PS	ABS, POM, PC and PS	Same
Reuse durability		Reusable Single Patient Use Only	Reusable Single Patient Use Only	Same
Disinfection Method		Super Sani-Cloth	Super Sani-Cloth or Discide® Ultra Disinfecting Wipes	Different 1
Label/Labeling		Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Main performance parameters	Penetration Depth	0.50~1.70±0.30mm（Model: HH-XV-T）	0.50~1.70±0.30mm（Model: HH-XV-T, Without Clear Cap）	Same
		3.2±0.30mm（Model: HH-XXVII-T, With AST Cap）	3.2±0.30mm（Model: HH-XV-T, With Clear Cap）	Same

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<td>Dimension</td>
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<tr><th>model</th><th>Total Length L1(± 2mm)</th><th>Tail end diameter D1(± 1mm)</th><th>Middle diameter D2(± 1mm)</th><th>Diameter of needle outlet D3(± 0.5mm)</th><th>Inner diameter of the needle fixed carriage D4(± 0.5mm)</th></tr>
<tr><td>HH-XV-T</td><td>107</td><td>18.3</td><td>16.6</td><td>3.0</td><td>6.1</td></tr>
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<tr><td>HH-XXVII-T</td><td>105</td><td>14.7</td><td>17</td><td>4</td><td>6</td></tr>
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<td>Different 2</td>
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<td></td>
<td>Mechanical loading and firing function</td>
<td>Cocking barrel with releasing button</td>
<td>Cocking barrel with releasing button</td>
<td>same</td>
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Explanation of differences:

Different 1:

The additional disinfectant (Discide® Ultra Disinfecting Wipes) has been validated for compatibility and efficacy. Material compatibility testing and simulated use cleaning were cosnducted, confirming no adverse impact on device performance, material integrity, or user safety. Therefore, this change does not raise new questions of safety or effectiveness.

Different 2:

The dimensional differences between the predicate model HH-XXVII-T and the proposed model HH-XV-T (e.g., overall length, diameters, and geometric contours) represent minor structural variations that do not affect the lancing device's fundamental technology, spring-driven firing mechanism, applied force, or blood-sampling performance. Verification testing confirmed that these dimensional differences do not impact usability, ergonomics, or functional safety, and therefore do not raise new questions of safety or effectiveness.
Discussion: 1.The expanded Indications for Use do not introduce any changes to the device's technological characteristics, including penetration depth, structural dimensions, firing mechanism, or applied force. The device operates with the same spring‑driven lancet actuation mechanism, and all key performance characteristics remain unchanged. 2.The additional disinfecting wipe, Discide® Ultra, is an EPA‑registered intermediate‑level disinfectant with the same active ingredient categories (quaternary ammonium compounds and isopropyl alcohol) as the previously used Super Sani‑Cloth®. Both wipes are approved for use on medical devices and effective against bloodborne pathogens, including HIV‑1, HBV, and HCV. Validation testing confirmed material compatibility and demonstrated that the introduction of the new wipe does not affect safety, device performance, or user instructions. Therefore, the proposed device does not raise new questions of safety or effectiveness compared to the predicate.

VII Non-Clinical Testing

Non-clinical verification and validation testing was conducted to support substantial equivalence of the modified device to the predicate device (K243306). All testing was performed using the same or equivalent protocols and acceptance criteria previously reviewed and cleared for the predicate.

Design Verification and Validation

Testing included, but was not limited to:

- Injection process verification report
- Performance test report
- Match Test Report
- Simulated Transportation Test report
- Accelerated aging test report
- After accelerate aging- Performance test report
- Cleaning and Disinfection Validation
- Simulated Clinical Use Testing Study Protocol and Report

1. Indication for Use Expansion

Testing included penetration depth verification, performance testing, and simulated-use validation on models. All testing followed the same protocols and acceptance criteria as the predicate device (K243306).

Results confirmed that the modified device meets its design specifications, and no new safety or effectiveness concerns were identified.

2. Disinfection Method Update

Cleaning and disinfection validation was conducted to evaluate the addition of Discide® Ultra Disinfecting Wipes as an alternative disinfectant. The evaluation consisted of repeated cleaning/disinfection cycles followed by visual examination and functional performance checks.

The results demonstrated no material degradation, no functional changes, and no negative impact on device usability or performance.

Therefore, the addition of the new disinfectant does not introduce new risks and does not raise new questions of safety or effectiveness.

3. Simulated Clinical Use

A simulated clinical use study was conducted using 500 device samples in accordance with the FDA Guidance *“Medical Devices with Sharps Injury Prevention Features”* (2005).

The device met all pre-established criteria for safety mechanism performance and user operation.
No use-related hazards or adverse events were identified.

VIII Clinical Testing
No clinical testing was required for this submission.

IX Conclusion

The proposed device and the predicate device have the same intended use and fundamental scientific technology.
All design changes—including the expanded Indication for Use and the additional disinfection method—have been fully verified and validated. Results demonstrate that the modified device:

- Meets all design input and performance requirements
- Does not introduce new safety or effectiveness concerns
- Is **substantially equivalent** to the predicate device (K243306)

Therefore, the proposed device is **as safe and effective** as the predicate device for its intended use.