August 18, 2026

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

Re: K262135
Trade/Device Name: Lancing device
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL
Dated: June 24, 2026
Received: June 25, 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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.08.18 11:16:36 -04'00'

Colin K. 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

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.	K262135

Please provide the device trade name(s).

Lancing device

Please provide your Indications for Use below.

Model: HH-XXXI-T
Without AST cap
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 AST cap
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.

Model: HH-XXXII-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.

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.
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Establishment Registration Number: 3009498536

Contact person: Ms. Ningning Wang
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Preparation date: June 25, 2026

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

The Lancing Device is a manually operated blood sampling device intended for use with sterile single-use lancets to obtain capillary blood samples for glucose and other blood testing requiring small amounts of blood.

The device family includes models with and without an Alternate Site Testing (AST) cap. Models without an AST cap are intended for obtaining capillary blood samples from the fingertip only. Models supplied with an AST cap may be used to obtain capillary blood samples from the fingertip, palm (at the base of the thumb), or forearm.

The Lancing Device is intended for single-patient use and must not be shared between users.

The housing and internal plastic components are manufactured from ABS, POM, PC, and PS resins. The spring is manufactured from carbon steel.

The device is supplied non-sterile and is intended for repeated use by a single patient in conjunction with sterile single-use lancets.

The subject device includes two additional models, HH-XXXI-T and HH-XXXII-T. The HH-XXXI-T model is technologically equivalent to the previously cleared HH-XIII-T model (without AST cap) and HH-XXVII-T model (with AST cap). Differences include external housing appearance, overall dimensions, and the number of depth adjustment settings. The HH-XXXI-T model provides eleven depth adjustment settings, whereas the HH-XIII-T and HH-XXVII-T models provide five depth adjustment settings.

The HH-XXXII-T model is technologically equivalent to the previously cleared HH-XVII-T model. The primary difference is the internal core structure. All other technological characteristics remain unchanged.

The newly added models utilize the same intended use, operating principle, lancet firing mechanism, patient-contacting materials, lancet compatibility, and depth adjustment function as previously cleared models included in K243306. The identified differences do not affect the safety or effectiveness of the device and do not raise different questions of safety or effectiveness.

V Indication for use

Model: HH-XXXI-T

Without AST cap

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 AST cap

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.

Model: HH-XXXII-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.

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-XIII-T, HH-XVII-T, HH-XXVII-T (K243306)	**Proposed device** Model: HH-XXXI-T, HH-XXXII-T	**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-XIII-T, HH-XVII-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-XXXI-T* **Without AST cap** 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	Same

	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 used by a single patient and should not be shared.	patient and should not be shared. **With AST cap** 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. *Model: HH-XXXII-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.	
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

Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Mechanical loading and firing function	Cocking barrel with releasing button	Cocking barrel with releasing button	Same
Penetration Depth	*Model: HH-XIII-T* 0.60~2.00±0.30mm	*Model: HH-XXXI-T* **Without AST cap** 0.45~1.95±0.30mm	Different
	Model: HH-XXVII-T, With AST Cap 3.2±0.30mm	*Model: HH-XXXI-T* **With AST cap** 3.2±0.30mm	Same
	Model: HH-XVII-T 0.6~1.8±0.30mm	*Model: HH-XXXII-T* 0.6~1.8±0.30mm	Same
Discussion: The HH-XXXI-T model has a slightly different penetration depth range (0.45–1.95 ± 0.30 mm) compared to the predicate HH-XIII-T model (0.60–2.00 ± 0.30 mm). This difference does not affect the intended use, operating principle, or blood sampling function of the device. The penetration depth remains within the range suitable for capillary blood sampling and does not raise different 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 Lancing Device models HH-XXXI-T and HH-XXXII-T.

The non-clinical testing program was designed to evaluate the safety and performance of the proposed devices and to demonstrate that they perform as intended when compared to the legally marketed predicate device (K243306). Testing addressed device functionality, penetration depth performance, durability.

Performance Testing

Performance testing was conducted to evaluate critical functional characteristics of the proposed lancing devices, including:

- Lancet loading and removal
- Device cocking and release mechanism operation
- Penetration depth adjustment performance
- Trigger mechanism functionality
- Penetration depth accuracy
- Repeated-use durability and life cycle performance

Performance testing confirmed that the modified depth adjustment configuration of HH-XXXI-T and the revised internal core structure of HH-XXXII-T do not adversely affect device functionality, penetration depth performance, or overall device reliability.

All tested samples met the predefined acceptance criteria and demonstrated performance equivalent to the predicate device.

Simulated Clinical Use Testing

A simulated clinical use study was conducted using 500 samples of the proposed lancing device 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 lancing device models HH-XXXI-T and HH-XXXII-T meet their design and performance specifications and are as safe and effective as the predicate device. The identified differences between the proposed and predicate devices do not raise different questions of safety or effectiveness.

VIII Clinical Testing

No clinical testing was required for this submission.

IX Conclusion

The proposed lancing device models HH-XXXI-T and HH-XXXII-T have the same intended use and technological characteristics as the predicate device (K243306).

Any differences between the proposed and predicate devices, do not affect the intended use, operating principle, or performance characteristics of the device.

Verification and validation testing demonstrate that the proposed devices meet all applicable design and performance requirements and perform as intended. The identified differences do not raise different questions of safety or effectiveness.

Based on the information provided in this submission, the proposed lancing device models HH-XXXI-T and HH-XXXII-T are substantially equivalent to the predicate device (K243306) and are as safe and effective for their intended use.