November 15, 2024

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: K243306
Trade/Device Name: Lancet (IA, IB, IC, ID, IE, IK, IL, IM, IIA, IIB, III, V, VI, VII, VIII, IX); Lancing device (HH-X-T, HH-XV-T, HH-XVI-T, HH-XVII-T, HH-XVIII-T, HH-XIX, HH-XXI-T, HH-XXII-T, HH-XXIII-T, HH-XXIV-T, HH-XXV-T, HH-XXVI-T, HH-XXVIII-T, HH-XXIX-T, HH-XXX-T, HH-XIII-T, HH-XXVII-T)
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL, QRK
Dated: October 17, 2024
Received: October 21, 2024

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.11.15 10:06:41 -05'00'

Long 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

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.

Submission Number *(if known)*

K243306

Device Name

Lancet (IA, IB, IC, ID, IE, IK, IL, IM, IIA, IIB, III, V, VI, VII, VIII, IX);
Lancing device (HH-X-T, HH-XV-T, HH-XVI-T, HH-XVII-T, HH-XVIII-T, HH-XIX, HH-XXI-T, HH-XXII-T, HH-XXIII-T, HH-XXIV-T, HH-XXV-T, HH-XXVI-T, HH-XXVIII-T, HH-XXIX-T, HH-XXX-T, HH-XIII-T, HH-XXVII-T)

Indications for Use *(Describe)*

Lancet:
The lancet is intended for capillary blood sampling.
Lancing device:
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. (HH-X-T, HH-XV-T, HH-XVI-T, HH-XVII-T, HH-XVIII-T, HH-XIX, HH-XXI-T, HH-XXII-T, HH-XXIII-T, HH-XXIV-T, HH-XXV-T, HH-XXVI-T, HH-XXVIII-T, HH-XXIX-T, HH-XXX-T, HH-XIII-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. (HH-XXVII-T)

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.

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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
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Tel.: +86-13021381776
E-mail: ningning.wang@hh-technology.com

Preparation date: October 17, 2024

II Proposed Device

Trade Name of Device:	Lancet, 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 and QRK
Review Panel	General & Plastic Surgery

III Predicate Devices

510(k) Number:	K220475
Trade name:	Lancet, Lancing device
Classification:	Class II
Product Code:	QRL, QRK
Manufacturer:	Tianjin Huahong Technology Co., Ltd.

IV Device description

Lancet

The Lancet (use with lancing device) is a single use, sterile medical device, which is designed for use of micro blood sampling puncture to obtain capillary blood samples from the fingertip.

The Lancet is composed three components: needle, main body and protective cap. Main body and protective cap is plastic part that enclosed the needle. The Lancet is intended to be single use and the needle tip is sterilized by Radiation. The shelf-life of the product is 5 years.

Lancing Device

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 Resin. And the spring is made of carbon steel.

The service life of the Lancing Device is 5 years or 5000 times of normal use, whichever comes first.

For Model HH-XIII-T, the service life of the Lancing Device is 10 years or 5000 times of normal use, whichever comes first.

The Lancing Device is provided non-sterile.

V Indication for use

Lancet

The lancet is intended for capillary blood sampling.

Lancing Device

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. (HH-X-T, HH-XV-T, HH-XVI-T, HH-XVII-T, HH-XVIII-T, HH-XIX, HH-XXI-T, HH-XXII-T, HH-XXIII-T, HH-XXIV-T, HH-XXV-T, HH-XXVI-T, HH-XXVII-T, HH-XXVIII-T, HH-XXIX-T, HH-XXX-T, HH-XIII-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. (HH-XXVII-T).

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&2:

Table 1 General Comparison of Lancet

Item	Predicate device (K220475)	Proposed device	Comments on Similarities/Differences	Safety/Effectiveness Statement
Product name	Lancet	No Change	N/A	No new concerns. The product name remains unchanged
Product Code	QRL and QRK	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 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	For the Lancet, stainless steel needle is fed into an injection molding machine to over-mold plastic material (polyethylene (PE) and Ethylene Vinyl Acetate (EVA) and calcium powder) forming a body and cap, encapsulating the stainless steel needles.	No Change	N/A	No new concerns. The manufacturing aspects remains consistent.

Design and Functionality aspects	The Lancet comprises a stainless steel needle encapsulated with a plastic body and cap, the cap is twisted off to expose the needle for use	No Change	N/A	No new concerns. The design and functionality aspects remains consistent.
Needle length range	3.2±0.3mm（Model：IA、IB、IC、ID、IE、IK、IL、IM、IIA、IIB、III、VI） 2.1±0.3mm（Model：V）	3.2±0.3mm（Model：IA、IB、IC、ID、IE、IK、IL、IM、 IIA、IIB、III、VI、VII） 2.1±0.3mm（Model：V） 2.2±0.3mm（Model：VIII, IX）	New three models of VII, VIII and IX were added.	No new concerns. Model VII can only be used in conjunction with our company's HH-XXV-T lancing device. After the performance test and the matching test, the product can be guaranteed to be safe and effective. Model VIII can only be used in conjunction with our company's HH-XXIX-T lancing device. After the performance test and the matching test, the product can be guaranteed to be safe and effective. Model IX can only be used in conjunction with our company's HH-XXX-T lancing device. After the

				performance test and the matching test, the product can be guaranteed to be safe and effective. Model IX is a little smaller than model VIII.
Gauge range	1.50±0.02mm（16G） 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）	New three size of 17G, 35G and 37G were added.	No new concerns. The added sizes are within the original approved sizes.

	0.24±0.01mm（32G） 0.21±0.01mm（33G） 0.19±0.01mm（34G） 0.17±0.01mm（36G） 0.15±0.01mm（38G）	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 aspects remains consistent.
Materials of parts in contact with human body	The Lancet has a needle that is made of stainless steel and a body and a cap that are made of polyethylene and Ethylene Vinyl Acetate (EVA) and calcium powder.	The Lancet has a needle that is made of stainless steel and a body and a cap that are made of polyethylene and Ethylene Vinyl Acetate (EVA) and calcium powder.	Material of body and a cap is added the PE which is only contact intact skin.	No new concerns. The raw materials added this time are the same as in K220475, all are PE, only the grades are different, and the human body surface is in contact with the complete skin, reviewed geometric changes per CDRH's Biocompatibility Guidance, That these materials pose a

				very low biocompatibility risk, and we have done the appropriate biological tests for this purpose, and the test results show that it meets the requirements.
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.

Table 2 General Comparison of Lancing device

Item	Predicate device (K220475)	Proposed device	Comments on Similarities/Differences	Safety/Effectiveness Statement
Product name	Lancing device	No Change	N/A	No new concerns. The product name remains unchanged
Product Code	QRL	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 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.	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. (HH-X-T, HH-XV-T, HH-XVI-T, HH-XVII-T, HH-XVIII-T, HH-XIX, HH-XXI-T, HH-XXII-T, HH-XXIII-T, HH-XXIV-T, HH-XXV-T, HH-XXVI-T, HH-XXVII-T, HH-XXVIII-T, HH-XXIX-T, HH-XXX-T, HH-XIII-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. (HH-XXVII-T)	Increase in Indication for Use (add palm and forearm) of the new model HH-XXVII-T	No new concerns because the additional intended use site of HH-XXVII-T (palm and forearm) was covered by the predicate device(K113332) of our predicate device (K220475)
Puncture device to obtain micro blood samples	Yes	No Change	N/A	No new concerns. The function is the same.

Lancet retracted after use to prevent sharp injure	Yes	No Change	N/A	No new concerns. The prevent sharp injure is the same.
Device penetration depth range	0.85~2.20±0.30mm（model HH-X-T） 0.60~2.00±0.30mm（model HH-XIII-T、HH-XXII-T） 0.50~1.70±0.30mm（model HH-XV-T） 0.60~1.95±0.30mm（model HH-XVI-T、HH-XXI-T、HH-XXIII-T、HH-XXIV-T） 0.60~1.80±0.30mm（model HH-XVII-T、HH-XIX） 0.60~2.10±0.30mm（model HH-XVIII-T）	0.85~2.20±0.30mm（model HH-X-T） 0.60~2.00±0.30mm（model HH-XIII-T、HH-XXII-T、HH-XXVI-T、HH-XXVII-T、HH-XXVIII-T） 0.50~1.70±0.30mm（model HH-XV-T） 0.60~1.95±0.30mm（model HH-XVI-T、HH-XXI-T、HH-XXIII-T、HH-XXIV-T） 0.60~1.80±0.30mm（model HH-XVII-T、HH-XIX、HH-XXV-T、HH-XXIX-T、HH-XXX-T） 0.60~2.10±0.30mm（model HH-XVIII-T）	New six models of HH-XXV-T, HH-XXVI-T, HH-XXVII-T, HH-XXVIII-T, HH-XXIX-T, and HH-XXX-T were added.	No new concerns. The newly added models are only changed in appearance and dimensions compared to K220475.
Mechanical loading and firing function	Cocking barrel with releasing button	No Change	N/A	No new concerns.

				The mechanical loading and firing function remains consistent.
Materials	ABS, POM, PC	ABS, POM, PC and PS	Increase in raw material PS	No new concerns. This addition of raw material PS will only come into contact with complete skin on the surface of the human body, reviewed geometric changes per CDRH's Biocompatibility Guidance, That these materials pose a very low biocompatibility risk because they have a long history of safe use in legally marketed medical devices that contact intact skin.
Reuse durability	Reusable Single Patient Use Only	No Change	N/A	No new concerns. The reuse durability remains consistent.
Sterilization method and SAL	NA	NA	N/A	N/A

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:

Sizes and model: Additional sizes ranging and model were introduced to meet clinical needs.

Material: The lancet body and cap material was changed to include PE to improve manufacturing efficiency. The new material was tested and found to be biocompatible and non-toxic as per ISO 10993-1.

Testing Performed:

Performance Testing: The lancet and lancing device underwent performance testing (reports HH-JS-RP-2024-03 and HH-JS-RP-2024-04), The testing confirmed that the lancet and lancing device meet the performance criteria outlined.

Biocompatibility Testing: The new PE material was tested for In Vitro cytotoxicity, skin sensitization, intracutaneous reactivity, acute systemic toxicity, and pyrogenicity according to ISO 10993-1 standards. The results confirmed that the material is non-toxic and safe for use in its intended application.

Simulated Clinical Use

A simulated clinical use study was performed on 640 device samples each for the Lancet and Lancing Device 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 lancet and lancing device 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 lancet and lancing device are substantially equivalent to

the predicate device K220475. The changes, including the addition of new needle sizes and the material change, 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.