July 22, 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: K262211
Trade/Device Name: Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL, QRK
Dated: June 29, 2026
Received: June 30, 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: 2026.07.22 10:27:28 -04'00'

Colin K. 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

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.	K262211

Please provide the device trade name(s).

Lancet

Please provide your Indications for Use below.

The 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: June 29, 2026

II Proposed Device

Trade Name of Device:	Lancet
Common name:	Multiple Use Blood Lancet For Single Patient Use Only Single use only blood lancet without an integral sharps injury prevention feature
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:	K243306
Trade name:	Lancet, Lancing device
Classification:	Class II
Product Code:	QRL, QRK
Manufacturer:	Tianjin Huahong Technology Co., Ltd.

IV Device description

The Lancet (use with a lancing device) is a sterile, single-use medical device intended for obtaining capillary blood samples by puncturing the fingertip.

The Lancet consists of three components: a needle, a main body, and a protective cap. The needle is enclosed within the plastic main body and protective cap. The plastic components are manufactured from medical-grade polyethylene (PE), with ethylene-vinyl acetate (EVA) and calcium carbonate-filled material optionally incorporated depending on the product configuration. This submission introduces additional qualified PE and EVA material grades as alternative raw materials. The needle tip is sterilized by radiation. The device is supplied sterile for single use only and has a shelf life of 5 years.

V Indication for use

The lancet is intended for capillary blood sampling.

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 General Comparison

Item	Predicate device (K243306)	Proposed device	Comments
Product name	Lancet	Lancet	Same
Product Code	QRL and QRK	QRL and QRK	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 lancet is intended for capillary blood sampling.	The 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	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)	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)	Same

	forming a body and cap, encapsulating the stainless steel needles.	forming a body and cap, encapsulating the stainless steel needles.	
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	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	Same
Needle length range	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）	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）	Same
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）	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）	Same

	0.31±0.01mm（30G） 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）	0.31±0.01mm（30G） 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	5 years	Same
Materials of parts in contact with human body	Needle: Stainless steel, silicone oil(optional) Plastic components (main body/protective cap): • PE (2102TN00 & JMC993P) or PE (SP-E50 P9W-T0178) • EVA (14-2) • Calcium powder	Needle: Stainless steel, silicone oil(optional) Plastic components (main body/protective cap): • PE (2102TN00 & JMC993P) or PE (Q281 & JMC993P) or PE (SP-E50 P9W-T0178) or PE (2911 & 2102TN00) or PE (2911 & Q281) or PE (Q281) or PE (2102TN00) • EVA (14-2 or V4110J) (optional) • Calcium powder (optional)	Different 1
Biocompatibility	Conforms to the requirements of ISO 10993 series standards.	Conforms to the requirements of ISO 10993 series standards.	Same
Performance requirements	The device meets the applicable performance requirements, including	The device meets the applicable performance requirements, including	Different 2

	needle dimensions, needle strength, penetration performance, drawing force (≥15 N for Models I, III, V and VI with 16G – 30G needles; ≥5 N for all other models and needle gauges), sterility, and package integrity.	needle dimensions, needle strength, penetration performance, drawing force (≥5 N for all models and needle gauges), sterility, and package integrity.	
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

Discussion:

Different1

The proposed device introduces additional qualified PE and EVA material grades and allows EVA and calcium carbonate-filled material to be optionally incorporated depending on the product configuration. These material changes do not alter the device's intended use, design, or fundamental scientific technology. Biocompatibility testing of the proposed device was conducted in accordance with the applicable ISO 10993 standards and demonstrated that the modified device continues to meet the applicable biological safety requirements. Therefore, the material modifications do not adversely affect the safety or effectiveness of the device and do not raise different questions of safety or effectiveness.

Different 2

The proposed device adopts a uniform drawing force acceptance criterion of ≥5 N for all models and needle gauges. Compared with the predicate device, the acceptance criterion for Models I, III, IV, V, and VI with 16G – 30G needles has been revised from ≥15 N to ≥5 N, while the acceptance criterion for all other models and needle gauges remains unchanged. Design verification, including drawing force testing and simulated clinical use testing, demonstrated that the revised acceptance criterion provides adequate mechanical integrity and reliable device performance during intended use. Therefore, the modification does not adversely affect the safety or effectiveness of the device and does not raise different questions of safety or effectiveness.

VII Non-Clinical Testing

7.1 Verification and Validation Activities – Design Changes

The proposed Lancet differs from the predicate device (K243306) by the addition of alternative polyethylene (PE) raw material grades, the addition of alternative ethylene-vinyl acetate (EVA) raw material grades, the revision of certain material components from mandatory to optional depending on product configuration, and the revision of the drawing force acceptance criterion revision of the drawing force acceptance criterion for certain models and needle gauges (16G–30G) from ≥15 N to ≥5 N. No changes were made to the intended use, fundamental operating principle, device design, sterilization method, or overall performance specifications.

Design verification and validation activities were conducted to evaluate the impact of these changes on device safety and performance in accordance with established design control procedures.

7.2 Non-Clinical Testing Overview

Non-clinical testing was performed to support the safety and performance of the modified device. The testing program included mechanical performance testing, drawing force testing, biocompatibility evaluation, simulated transportation testing, packaging integrity testing, accelerated aging testing, and post-aging performance testing.

All testing was conducted in accordance with internal specifications and applicable standards. Acceptance criteria were established based on the predicate device specifications and applicable regulatory and consensus standards.

7.3 Simulated Clinical Use Testing

A simulated clinical use study was conducted to evaluate device performance under simulated use conditions and to assess the impact of the revised drawing force acceptance criterion and material configuration changes.

The study involved both professional and non-professional users and utilized a synthetic skin model to simulate intended use conditions.

All tested devices successfully completed the simulated use evaluation without any observed abnormalities, including needle separation, loosening, activation failure, or functional malfunction.

7.4 Test Results Summary

All non-clinical verification and validation activities met their predefined acceptance criteria. Mechanical performance, biocompatibility, packaging integrity, and simulated use performance were demonstrated to be equivalent to the predicate device.

The revised uniform drawing force acceptance criterion (≥5 N) was confirmed to provide adequate mechanical integrity without adversely affecting device performance.

7.5 Conclusions

The results of non-clinical testing demonstrate that the proposed Lancet is substantially equivalent to the predicate device (K243306). The design modifications, including additional raw material grades, optional material configurations, and revised drawing force acceptance criterion, do not raise new questions of safety or effectiveness and do not adversely affect device performance or intended use.

VIII Clinical Testing

No clinical study is included in this submission.

IX Conclusion

Based on the design verification and validation activities, non-clinical performance testing, biocompatibility evaluation, and simulated clinical use testing, the proposed Lancet was demonstrated to meet all predefined acceptance criteria. The addition of alternative raw material grades, the revision of material configurations, and the modification of the drawing force acceptance criterion do not alter the device's intended use, fundamental scientific technology, or overall device design, and do not adversely affect its safety, effectiveness, or performance.

In conclusion, the proposed device is substantially equivalent to the predicate device (K243306). The design modifications do not raise different questions of safety and effectiveness, and the proposed device is as safe and effective as the legally marketed predicate device.