June 20, 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: K241627
Trade/Device Name: Safety Lancet (Model XXXV)
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: June 6, 2024
Received: June 6, 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.

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: 2024.06.20 12:01:35 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
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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.

Submission Number *(if known)*

K241627

Device Name

safety lancet (XXXV)

Indications for Use *(Describe)*

The safety lancet is intended for capillary blood sampling.

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.

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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: June 6, 2024

II Proposed Device

Trade Name of Device:	Safety Lancet (XXXV)
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:	K220370
Trade name:	Safety Lancet
Classification:	Class II
Product Code:	FMK
Manufacturer	Tianjin Huahong Technology Co., Ltd.

IV Device description

The safety lancet is single use medical device, which is designed to collect capillary blood sample.

The intended users include Healthcare personnel, patients and lay persons.

Model XXXV, the safety lancets consist of needle core, button, housing and spring.

The sterile part of the safety lancet is the needle tip.

The sterile barrier is the needle sleeve 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.

V Indication for use

The safety lancet is intended forcapillary blood sampling.

VI Comparison of technological characteristics with the predicate devices

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

Table 1 General Comparison of Safety Lancet

Item	**Proposed device**	**Predicate device (**K220370**)**	**Discussion**
Product name	Safety Lancet	Safety Lancet	Same
Product Code	FMK	FMK	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 safety lancet is intended for capillary blood sampling.	The safety lancet is intended for capillary blood sampling.	Same
Safety protection features	Yes	Yes	Same

510(k) Summary

Reuse durability	Single use	Single use	Same
Sterilization method and SAL	Sterilized by Radiation SAL=10^{-6}	Sterilized by Radiation SAL=10^{-6}	Same
Self-life	5 years	5 years	Same
Materials of parts in contact with human body	Needle core （contain needle）: PE, PP, Calcium powder, stainless steel (needle)，silicone oil (needle); Housing, Button: ABS, PS, PP and Calcium powder	Needle core （contain needle）: PE, PP, Calcium powder, stainless steel (needle)，silicone oil (needle); Housing, Button, Bottom, Small lid, Depth adjuster ring, Protective cap: ABS, PS	Similar[1]
Biocompatibility	Conforms to the requirements of ISO 10993 series standards.	Conforms to the requirements of ISO 10993 series standards.	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

[1] The raw materials of proposed devices may be different from the predicate devices. However, all the materials are known biocompatible materials that have been used in lancets or other similar medical devices.

VII Non-Clinical Testing

The bench testing performed verifies that the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device in terms of critical performance characteristics. These tests are as follow.

Launch performance	Launch performance should begood, launch button press smoothly, no jam	Meet the requirement
Puncture force	The needle tip of the needle should have good puncture ability.	Meet the requirement
Lubricant	Visual, should not be visible droplets.	Meet the requirement
Disposable	Safety lancet should be single use, no second launch after used.	Meet the requirement
Safety Feature	The force to activate the safety feature ： 4 - 15N Test access to the sharp: the needle shall not touch the sphere.	Meet the requirement

Biocompatibility Testing:

The biocompatibility evaluations were conducted in accordance with the 2020 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 safety lancet products (K220370) 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 Systemic Toxicity
Pyrogenicity	ISO 10993-11: 2017	no thermogenic reaction

Simulated Clinical Use

A simulated clinical use study was performed on 300 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.

VIII Clinical Testing

No clinical study is included in this submission.

IX Conclusion

The proposed device has the same indication for use and has similar design features and technological characteristic as the predicate device. Performance testing data demonstrates that the proposed device is safety and effectiveness as the predicated device. Accordingly, the proposed device is substantially equivalent to the predicate device.