



May 19, 2022

Tianjin Huahong Technology Co., Ltd.
% Ms. Stuart Situ
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd
Room 1308, Baohua International Plaza, West Guangzhong Road
555, Jingan District
Shanghai, 200072
China

Re: K220370

Trade/Device Name: Safety Lancet (8 Models: XIII, XVII, XXI, XXII, XXIII, XXIV, XXV, XXVI)
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual Surgical Instrument for General Use
Regulatory Class: Class II
Product Code: FMK
Dated: April 18, 2022
Received: April 18, 2022

Dear Ms. Situ:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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

510(k) Number (if known)

K220370

Device Name

Safety Lancet (8 models: XIII, XVII, XXI, XXII, XXIII, XXIV, XXV, XXVI)

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@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-K220370

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

Primary Contact person

Ms. Ying Yuan

Quality Manager

Tel.: +86-15302127671

E-mail: ying.yuan@hh-technology.com

Submission Correspondent

Ms. Stuart Situ

Director

Landlink Healthcare Technology (Shanghai) Co., Ltd.

Tel.: +86-13636633633

E-mail: stuart.situ@landlink-healthcare.com

Preparation date: Jan 28, 2022

II Proposed Device

Trade Name of Device: Safety Lancet (8 models: XIII, XVII, XXI, XXII, XXIII, XXIV, XXV, XXVI)

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: K192666

Trade name: VeriFine Safety Lancet
 Classification: Class I
 Product Code: FMK
 Manufacturer Promisemed Hangzhou Meditech 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.

According to surface difference or structure, the Safety lancets have 8 models: XIII, XVII, XXI, XXII, XXIII, XXIV, XXV, XXVI. XVII model have sub model according to surface difference.

For Model XIII, XVII, XXI, XXII, XXV, the safety lancets consist of needle core, button, housing, bottom, spring and protective cap. For Model XXIII, the safety lancets consist of needle core, button, housing, and spring. For Model XXIV, the safety lancets consist of needle core, button, housing, spring and ring. And for Model XXVI, the safety lancets consist of needle core, button, housing, small lid 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 for capillary blood sampling.

VI Comparison of technological characteristics with the predicate devices

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

Table 1 General Comparison of Safety Lancet

Item	Proposed device	Predicate device (K192666)	Discussion
Product name	Safety Lancet	VeriFine Safety Lancet	Same
Product Code	FMK	FMK	Same

Regulation No.	21 CFR § 878.4850	21 CFR § 878.4800	Similar ¹
Class	II	I	Similar ¹
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.	It is intended for capillary blood sampling.	Same
Safety protection features	Yes	Yes	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
Self-life	5 years	5 years	Same
Materials of parts in contact with human body	Needle core (contain needle) : PE,PP, Calcium powder(main ingredient: calcium carbonate), stainless steel (needle) , silicone oil (needle); Housing, Button, Bottom, Protective cap, Small lid, Depth adjuster ring: ABS,PS	Needle: stainless steel Other parts: plastics materials	Similar ²
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 classification and Regulation number are different because FDA issued the

final order about Reclassification of Blood Lancets on 11/22/2021.

² 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.

Items	Acceptance criteria	Results
Appearance	The surface shall be free of burr and no scratches.	Meet the requirement
Dimension	Product dimensions shall be consistent to the drawings	Meet the requirement
Cleanness	No dust, no grease, no hair, no dirt	Meet the requirement
Firmness	Needle should connect firmly with plastic handle:	Meet the requirement
Resistance to corrosion	Corrosion resistance of needle of lancet shall show no evidence of corrosion.	Meet the requirement
Acidity or Alkalinity	The pH value of an extract prepared refers to ISO 9626 Annex A shall be within one pH unit of that of the control fluid.	Meet the requirement
Limits for Extractable Metals	When corrected for the metals content of the control fluid, contain not greater than a combined total of 5 mg/l of lead, tin, zinc and iron. The cadmium content of the extract shall, when corrected for the cadmium content of the control fluid, be lower than 0.1 mg/l.	Meet the requirement
Puncture depth	Use calipers to measure and meet the requirements.	Meet the requirement
Launch performance	Launch performance should be good, 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:

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 500 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.