May 17, 2022

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

Re: K220372
Trade/Device Name: Heel Stick Safety Lancet (HHZ-II, HHZ-III)
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual Surgical Instrument For General Use
Regulatory Class: Class II
Product Code: FMK
Dated: January 28, 2022
Received: February 9, 2022

Dear Stuart 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K220372

Device Name

Heel Stick Safety Lancet (HHZ-II, HHZ-III)

Indications for Use *(Describe)*

Heel Stick Safety Lancet is intended for the collection of capillary blood from the heel of newborn, preemie, and toddler. The lancet has equipped with safety protection features.

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-K220372

I Submitter

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Preparation date: Jan 28, 2022

II Proposed Device

Trade Name of Device:	Heel Stick Safety Lancet (HHZ-II,HHZ-III)
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:	K210745
Trade name:	Heel Incision Safety Lancet
Classification:	Class I
Product Code:	FMK
Manufacturer	SteriLance Medical(Suzhou) Inc.

IV Device description

The heel stick safety lancet is offered in various depth size (0.65mm, 0.85mm, 1.00mm, 1.50mm) and width size (1.50 mm, 1.75mm, 2.50 mm, 2.80 mm).

It consists of blade base, blade, which is welded with the blade base, spring, top head, bottom, and pushing button. The top head and bottom are intended to provide physical protection to the blade, and PET blister along with the tyvek paper cover the primary sterile barrier system for the device. The product is individually primarily packaged 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.

Heel stick safety lancet is intended to be used by professionals. The product is intended for prescription (Rx) only.

V Indication for use

Heel Stick Safety Lancet is intended for the collection of capillary blood from the heel of newborn, preemie, and toddler. The lancet has equipped with safety protection features.

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 Heel Stick Safety Lancet

Item	**Proposed device (K220372)**	**Predicate device (K210745)**	**Discussion**
Product name	Heel Stick Safety Lancet (HHZ-II,HHZ-III)	Heel Incision 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	Prescription Use	Prescription Use	Same

Indication for use	Heel Stick Safety Lancet is intended for the collection of capillary blood from the heel of newborn, preemie, and toddler. The lancet has equipped with safety protection features	Heel Incision Safety Lancet is intended for the collection of capillary blood from the heel of newborn, preemie, and toddler. The lancet has equipped with safety protection features	Same
Applicable user	Newborn, preemie, and toddler	Newborn, preemie, and toddler	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
Component	1. Blade 2. Blade base 3. Top head 4. Bottom 5. Pushing button 6. Spring	1. Triggering button 2. Safety button/Screw button 3. Spring 4. Cam 5. Lancet core 6. Shell 7. Blade 8. Swing arm	Similar[2]
Incision Depth*Width	0.65*1.50 mm 0.85*1.75 mm 1.00*2.50 mm 1.50*2.80 mm	0.65*1.40 mm 0.85*1.75 mm 1.00*2.50 mm 1.14*2.80 mm 2.00*3.00 mm	Similar[3]

Materials of parts in contact with human body	Blade: stainless steel Top head: ABS Bottom: ABS Pushing bottom: ABS	Blade:304 stainless steel Shell: ABS Triggering button: ABS Safety button: ABS	Same
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 component of proposed devices is different from the predicate devices. However, the performance test for proposed device has been conducted as same as predicate device. The Safety feature performance specification for predicate device is a little difference. However, the safety feature performance test for proposed device has been evaluated and the test result conforms to requirements of ISO 23908:2011 standards. Therefore, the difference on configuration and materials does not affect substantially equivalence.

[3] The Incision depth and width of proposed devices is different from the predicate devices. However, the performance test for proposed device has been conducted as same as predicate device. And the depth and width of the proposed devices is covered by the predicated devices. Therefore, the difference on configuration and materials does not affect substantially equivalence.

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 product color shall be correct, with the surface without burr and scratches	Meet the requirement
Cleanness	The product shall be cleaned	Meet the requirement
Dimension	HHZ-II :	Meet the

	length：32.0mm±1.0mm；width：11.5mm±0.5mm HHZ-III : length：36.65mm±0.5mm；width：11.6±0.5mm	requirement
Firmness	Blade and blade base shall be firmly connected.	Meet the requirement
Launch performance	Launch performance should be good, launch button press smoothly, no jam	Meet the requirement
Launch depth and Launch width	Launch depth and launch width shall meet the requirements.	Meet the requirement
Force to activate the safety feature	4 - 10N	Meet the requirement
Testing access to the sharp in safe mode	The blade 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 600 device samples each for the Heel Stick 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.