July 6, 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: K220475
Trade/Device Name: Lancet (I, II, III, V, VI); Lancing device (HH-X-T, HH-XIII-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)
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL, QRK
Dated: June 6, 2022
Received: June 6, 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,

Colin Chen
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

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.

510(k) Number *(if known)*
K220475

Device Name
Lancet (I, II, III, V, VI);
Lancing device (HH-X-T, HH-XIII-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)

Indications for Use *(Describe)*
Lancet:
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.

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-K220475

I Submitter

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Preparation date: Feb 15, 2022

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:	K192666
Trade name:	Promosemed Blood Lancet
Classification:	Class II
Product Code:	FMK
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd.

510(k) Number:	K113332
Trade name:	On Call® Lancing Device
Classification:	Class II
Product Code:	FMK
Manufacturer	ACON Laboratories, Inc.

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 (made of stainless steel and silicone oil), main body and protective cap (both made of PE, EVA and calcium powder). 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 collect a capillary blood sample. The body and the active parts of the lancing device are made of ABS, POM and PC Resin. And the spring is made of carbon steel.

The service life of lancing device (HH-X-T, HH-XIII-T, HH-XV-T, HH-XVI-T, HH-XVIII-T, HH-XIX, HH-XXI-T, HH-XXII-T, HH-XXIII-T, HH-XXIV-T) is no more than 3000 times or 3 years. The service life of lancing device (HH-XVII-T) is no more than 5000 times or 5 years. The Lancing Device is provided non-sterile.

V Indication for use

Lancet

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.

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&2:

Table 1 General Comparison of Lancet

Item	Proposed device	Predicate device	Discussion

	(K220475)	**(K192666)**	
Product name	Lancet	Promosemed Blood Lancet	Same
Product Code	QRL and QRK	FMK	Different[1]
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	It is intended for capillary blood sampling	It 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) forming a body and cap, encapsulating the stainless steel needles.	For the Promisemed Blood Lancet, stainless steel needle is fed into an injection molding machine to over-mold plastic material (polyethylene) forming a body and cap, encapsulating the stainless steel needles.	Same
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	The Promisemed Blood Lancet comprises a stainless steel needle encapsulated with a plastic body and cap, the cap is	Same

	needle for use	twisted off to expose the needle for use	
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）	unknown	Different[2]
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） 0.24±0.01mm（32G） 0.21±0.01mm（33G） 0.19±0.01mm（34G）	unknown	Different[2]
Shelf-life	5 years	5 years	Same
Materials of parts in contact with human body	The Lancet has a needle that is made of stainless steel and silicone oil. The body and cap are made of polyethylene (PE) and Ethylene Vinyl Acetate (EVA)	The Promisemed Blood Lancet has a needle that is made of stainless steel and a body and a cap that are made of polyethylene (PE).	Similar[2]

	and calcium powder.		
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 product code is different because FDA issued the final order about Reclassification of Blood Lancets on 11/22/2021. Three new codes have been added of Blood Lancets. The product code QRL (Multiple Use Blood Lancet For Single Patient Use Only) and QRK (Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature) are closer to the purpose of our device.

[2] The component and material of proposed devices is different from the predicate devices. However, all the materials are known biocompatible materials that have been used in lancets or other similar medical devices. After the comparison test of the I-type needle of our device and the predicate device, the result shows that the length of the exposed tip of this product (3.2±0.3mm) is similar to that of the predicate device, see the comparison test report (No.: VC-22032202). Model V (the length of the exposed tip is 2.1±0.3mm) can only be used in conjunction with the company's HH-XVIII-T lancing pen. After the performance test and the matching test, the product can be guaranteed to be safe and effective.

[3] The needle length range or gauge range of the predicate device are unknown. There may be some differences between predicate device and proposed device. But the durability and strength of the needles were tested in a series of penetration tests using the proposed device, which shows positive result in these testing. Therefore, the differences do not raise concerns related to the device safety and effectiveness.

Table 2 General Comparison of Lancing device

Item	**Proposed device (K220475)**	**Predicate device (K113332)**	**Discussion**
Product name	Lancing device	Genteel Lancing device	Same
Product Code	QRL	FMK	Different[1]
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 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 On Call® Lancing Device is used with On Call® disposable sterile lancets to draw capillary blood from the fingertip, palm (at the base of the thumb) or forearm, for blood glucose testing or other testing utilizing small amounts of blood. The On Call® Lancing Device is intended to be used by a single patient and should not be shared.	Same
Puncture device to obtain micro blood samples	Yes	Yes	Same
Lancet retracted after use to prevent sharp injure	Yes	Yes	Same
Device penetration depth range	0.85mm(±0.30mm)~2.20mm(±0.30mm) (Model: HH-X-T); 0.60mm(±0.30mm)~2.00mm(±0.30mm) (Model HH-XIII-T、HH-XXII-T); 0.50mm(±0.30mm)~1.70mm(±0.30mm) (Model HH-XV-T); 0.60mm(±0.30mm)~1.95mm(±	unknown	Different[4]

	0.30mm) (Model HH-XVI-T、HH-XXI-T、HH-XXIII-T、HH-XXIV-T); 0.60mm(±0.30mm)~1.80mm(±0.30mm) (Model HH-XVII-T、HH-XIX); 0.60mm(±0.30mm)~2.10mm(±0.30mm) (Model HH-XVIII-T)		
Mechanical loading and firing function	Cocking barrel with releasing button	Cocking barrel with releasing button	Same
Materials	ABS, POM and PC Resin	ABS	Similar[5]
Reuse durability	Reusable Single Patient Use Only	Reusable Single Patient Use Only	Same
Sterilization method and SAL	NA	NA	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

[4] The Device penetration depth range of the predicate device is unknown. Krleza et al.[1] recommended that if the recommended puncture site is finger, the recommended incision depth is up to 1.5mm for child aged 6 months to 8 years, and up to 2.4mm for child older than 8 years and adults; if the recommended puncture site is heel, the recommended incision depth is up to 0.85mm for premature neonates(up to 3kg), and up to 2.0mm for infants under 6 months of age. The puncture depth of the product ranges from 0.50mm (±0.30mm) to 2.2mm (±0.30mm) covers the requirements of recommended incision depth. Therefore, this differences in the subject and predicate device do not raise concerns related to device safety and effectiveness.

[5] The raw materials of proposed devices may different from the predicate devices. However, all the materials are medical grade 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
Needle diameter	The diameter of the needle shall be consistent to the requirement	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	When determined with a laboratory pH meter and using a general purpose electrode, the pH value of an extract prepared shall be within one pH unit of that of the control fluid.	Meet the requirement
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 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
Matching	It should be well assembled with the lancing devices, with no dislocation in	Meet the requirement

	the appearance coordination.	

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 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.

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.