January 23, 2023

Huaian Hening Medical Instruments Co., Ltd
Zhengcan Da
General Manager
No. 6 West Hongdou Road Economic Development Zone
Huaian, Jiangsu
China

Re: K223313
Trade/Device Name: Disposable Safety Lancets
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: December 29, 2022
Received: December 29, 2022

Dear Zhengcan Da:

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,

Jessica Carr -S

for 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.

510(k) Number *(if known)*
K223313

Device Name
Disposable Safety Lancets

Indications for Use *(Describe)*
Disposable Safety Lancets
The product is used to obtain capillary blood samples from fingertip in a hospital or at home. The device contains a sharp injury protection feature.

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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K223313 510(k) summary

I Submitter

Device submitter: HUAIAN HENING MEDICAL INSTRUMENTS CO., LTD.
NO.6 West Hongdou Road Economic Development Zone Huaian, Jiangsu China

Contact person: Zhengcan Da
General Manager
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Date: 10/12/2022

II Device

Trade Name of Device: Disposable Safety Lancets
Common Name: Blood Lancets
Regulation Number: 21 CFR 878.4850
Regulation Name:
Single Use Only Blood Lancet with an Integral Sharps Injury Prevention Feature
Regulatory Class: II
Product code: FMK
Review Panel: General & Plastic Surgery

III Predicate Devices

Trade name:	SurgiLance® Safety Lancets
Common name:	Blood Lancets
Classification:	I-Lancet with Sharps Prevention Feature, 21CFR 878.4800
Product Code:	FMK
Premarket Notification:	K101145
Manufacturer:	MediPurpose Pte, Ltd.

IV Device description

The Disposable Safety Lancets consists 7 parts, include a trigger, plastic handle, out shell, back cover, spring, protective cap and needle. The models of the Disposable Safety Lancets are 21G; 23G; 26G; 28G; 30G. The product is used to obtain capillary blood samples from fingertip in a hospital or at home. The device contains a sharp injury feature. The lancet is hit by pressure, and once the device strikes, the lancet needle can

puncture the skin. And once activated, the needle retracts into the body of the device which reduces the risk of injury as the result if an exposed needle. Used Gamma sterilization, and are products for single use.

V Indications for use

Disposable Safety Lancets

The product is used to obtain capillary blood samples from fingertip in a hospital or at home. The device contains a sharp injury protection feature.

VI Comparison of technological characteristics with the predicate devices

The Disposable Safety Lancets have the same intended use, technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices. The differences between the Disposable Safety Lancets and predicate devices do not alter suitability of the proposed device for its intended use.

Device feature	**Subject Device** **(Disposable Safety Lancets)**	**Predicate Device K101145** **（SurgiLance® Safety Lancets）**	**Comment**
Indications for use	The product is used to obtain capillary blood samples from fingertip in a hospital or at home. The device contains a sharp injury protection feature.	The SurgiLance® Safety Lancet is a puncture device to obtain micro blood samples. The SurgiLance® Safety Lancet has a sharps prevention feature to protect the user from a needlestick injury.	Similar Comment 1
Product code	FMK	FMK	Equivalent
Safety protection features	Yes	Yes	Equivalent
Reuse durability	Single use	Single use	Equivalent
Sterilization	Irradiation	Not available	Different Comment 2

Device feature	Subject Device (Disposable Safety Lancets)	Predicate Device K101145 （SurgiLance® Safety Lancets）	Comment
Model	21G; 23G; 26G; 28G; 30G	SLN 100: 21G; SLN 200: 21G; SLN 240: 21G; SLN 300: 21G; SLB 200: 18G; SLB 250: 18G; (Information gathered from MediPurpose Pte, Ltd. official website)	Different Comment 3
Launch length	21G-2.2mm 23G-1.8mm 26G-1.8mm 28G-1.8mm 30G -1.8mm	SLN 100: 21G-1.0mm SLN 200: 21G-1.8mm SLN 240: 21G-2.2mm SLN 300: 21G-2.8mm SLB 200: 18G-1.8mm SLB 250: 18G-2.3mm	
Materials of parts in contact with human body	Lancet needle: 304 austenitic stainless steel; Body and cap: ABS;	Lancet needle: medical grade stainless steel; Housing and cap: plastics	Similar Comment 4

Discussion:

Comment 1

The subject device and the predicate device have the same intended use, to puncture the skin to obtain drops of blood for testing purposes. The same basic technology characteristics for a lancet with sharps injury prevention of Disposable Safety Lancets as compared with the predicate device.

Comment 2

The sterilization method of predicate device is not available. However, the subject device was ensured sterility by sterilization validation. Therefore, the differences on sterilization do not raise new questions about safety and effectiveness.

Comment 3

The models and Launch length of subject device are different from the predicate device. The model was more than as the predicated products, while the puncture depths are same. Different models are only different in the outer diameter of the needle, which allowed to choose to meet blood volume needs. Different needle specification will be selected by physician per patient's condition and this different were addressed by performance tests. Testing of performance shows no impact of launch length on the sharpness /penetration force or bond between the lancet body and needle, this difference does not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

Comment 4

The subject device utilizes some of the same materials, specifically the use of medical grade stainless steel for the lancet needles but may use different types plastics for the bodies, caps. All the materials are known biocompatible materials that have been used in lancets or other similar medical devices, and the materials of subject device were demonstrated by the biocompatibility tests done. The differences between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

VII Summary of non-clinical testing

The following performance data were provided in support of the substantial equivalence determination.

Performance Testing for Disposable Safety Lancets

No	Testing item	Specification	Result
01	Appearance	Disposable Safety Lancets the surface should be smooth without edge, no dirt and damage, deformation and other poor appearance.	Pass
02	Launch Length	The length of the needles in the Disposable Safety Lancet is different in different gauges.	Pass

		The launch length of the needle is determined according to the length of the purchase, and the general emission length is 1.8mm-2.2mm.	
03	Sharpness/Penetration testing	Penetration force ⩽1.00N.	Pass
04	Feature	The tip of the needle can shrink quickly after firing, and the tip of the needle is not exposed.	Pass
05		Disposable Safety Lancets Only one launch, not another.	Pass
06	Initial bioburden	Initial bioburden of the device shall be less than 100CFU/g	Pass
07	Sterile	The sterile blood lancet shall be sterile	Pass
08	Cap removal force	The moment for breaking the safe mode should range from 30 N*cm to 35 N*cm.	Pass
09	Needle removal force	The bond between the lancet body and needle should be greater than or equal to 10N/15s.	Pass
10	Drop testing	The carton box should have no puncture after the drop test.	Pass

Biocompatibility testing

Biocompatibility of the Disposable Blood Lancets and Disposable Safety Lancets were evaluated in accordance with ISO 10993-1:2018 for the body contact category. The following tests were performed, as recommended:

Cytotoxic test	ISO 10993-5:2009
Skin sensitization test	ISO 10993-23:2021
Intracutaneous test	ISO 10993-10:2021
Acute systemic toxicity test	ISO10993-11:2017
Hemolysis test	ISO 10993-4:2017
Pyrogen Test	ISO10993-11:2017

Sterilization and shelf life testing

- Irradiation sterilization validation per ISO 11137-1 and ISO 11137-3.
- Pyrogen testing per ISO 10993-11:2017
- Simulated shipping per ISTA 2A: 2011
- The 5 years shelf life of the device is determined based on stability study which includes ageing test.

VIII Conclusion

The Disposable Safety Lancets is substantially equivalent to its predicate device (SurgiLance® Safety Lancets). The differences between the predicate and subject device do not raise any new or different questions of safety or effectiveness. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.