January 25, 2023

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

Re: K223314
Trade/Device Name: Disposable Blood Lancets
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRK, QRL
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, PhD
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)*
K223314

Device Name
Disposable Blood Lancets

Indications for Use *(Describe)*
Disposable Blood Lancets
The product is used to obtain capillary blood samples from fingertip in a hospital or at home. The lancet is assembled with lancing device, once the lancing device is launched, the needle of lancet can prick the skin.

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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K223314 510(k) summary

I Submitter

Device submitter: HUAIAN HENING MEDICAL INSTRUMENTS CO., LTD.
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Contact person: Zhengcan Da
General Manager
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Email: hn-lancets@vip.163.com

Date: 10/12/2022

II Device

Trade Name of Device: Disposable Blood Lancets
Common Name: Blood Lancets
Regulation Number: 21 CFR 878.4850
Regulation Name:
Single Use Only Blood Lancet without an Integral Sharps Injury Prevention Feature
Regulatory Class: II
Product code: QRK; QRL
Review Panel: General & Plastic Surgery

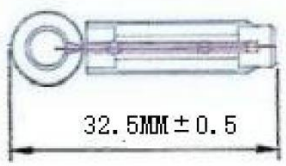
III Predicate Devices

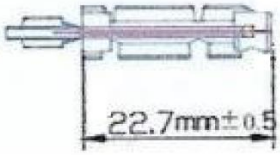
Trade name:	Promisemed Blood Lancet VeriFine Safety Lancet VeriFine Mini-Safety Lancet
Common name:	Blood Lancet
Classification:	Class I, Lancet, Blood, 21CFR 878.4800
Product Code:	FMK
Premarket Notification:	K192666
Manufacturer:	Promisemed Hangzhou Meditech Co., Ltd.

IV Device description

The Disposable Blood Lancets consists of a needle, a body and a cap. The models of the Disposable Blood Lancets are 21G; 23G; 26G; 28G; 30G. Disposable Blood Lancets

are used to obtain blood samples for testing purposes. It is sterilized by Irradiation and is a single-use product. The device is compatible with the reusable lancing device which met the specification and size requirements of the following figure in the market.





V Indications for use

The product is used to obtain capillary blood samples from fingertip in a hospital or at home. The lancet is assembled with lancing device, once the lancing device is launched, the needle of lancet can prick the skin.

VI Comparison of technological characteristics with the predicate devices

The Disposable Blood 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 Blood Lancets and predicate devices do not alter suitability of the proposed device for its intended use.

Device feature	Subject Device (Disposable Blood Lancets)	Predicate Device K192666 (Promisemed Blood Lancet)	Comment
Indications for use	The product is used to obtain capillary blood samples from fingertip in a hospital or at home. The lancet is assembled with lancing device, once the lancing device is launched, the needle of lancet can prick the skin.	It is intended for capillary blood sampling.	Similar Comment 1
Product code	QRK, QRL	FMK	Different Comment 1
Safety protection features	No	Yes	Different

Device feature	Subject Device (Disposable Blood Lancets)	Predicate Device K192666 (Promisemed Blood Lancet)	Comment
			Comment 1
Reuse durability	Single use	Single use	Equivalent
Sterilization	Irradiation	Not available	Different Comment 2
Model	21G; 23G; 26G; 28G; 30G	BL-30 (30G) BL-28 (28G) (Information gathered from Promisemed Hangzhou Meditech Co., Ltd. official website)	Different Comment 3
Launch length	3.2mm±0.6	3mm (Information gathered from Promisemed Hangzhou Meditech Co., Ltd. official website)	
Materials of parts in contact with human body	Lancet needle: stainless steel; Body and cap: PE	Lancet needle: stainless steel; Body and cap: PE	Equivalent
Principle of Operation	The Disposable Blood Lancets comprises a stainless steel needle encapsulated with a plastic body and cap, the cap is twisted off to expose the needle for use.	The Promisemed Blood Lancet comprises a stainless steel needle encapsulated with a plastic body and cap, the cap is	Equivalent

Device feature	Subject Device (Disposable Blood Lancets)	Predicate Device K192666 (Promisemed Blood Lancet)	Comment
		twisted off to expose the needle for use.	
Manufacturing	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. Terminal sterilization process is performed to ensure sterility of an entire product.	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. Terminal sterilization process is performed to ensure sterility of an entire product.	Equivalent

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. While the Disposable Blood Lancets have no sharp's prevention features and without the intended use of protecting the user from a needlestick injury. This difference does not affect the clinical safety of the subject 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 because the puncture depth is tuned by the lancing device, not the lancet itself, 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.

VII Summary of non-clinical testing

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

No	Testing item	Specification	Result
01	Appearance	Lancet should have the same color, no bubble, no flash, no slip.	Pass
02	Launch Length	The length of the needles in the Disposable Blood Lancets is different in different gauge. The general depth is 3.2mm	Pass
03	Sharpness/Penetration testing	Penetration force ≤1.00N.	Pass
04	Exterior	The connection between needle and needle body should be firm.	Pass
05		Cap twist should be smooth.	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
- Transportation test 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 Blood Lancets is substantially equivalent to its predicate device (Promisemed Blood Lancet). 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.