September 19, 2022

Hebei Xinle Sci&Tech Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.Box 120-119
Shanghai, 200120
China

Re: K221839
Trade/Device Name: Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood lancets
Regulatory Class: Class II
Product Code: FMK
Dated: June 21, 2022
Received: June 24, 2022

Dear Diana Hong:

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,

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)*

K221839

Device Name
Lancet

Indications for Use *(Describe)*
It 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:

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"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."

Tab # 6 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number:_____

1. Date of Preparation: 06/21/2022

2. Sponsor Identification

Hebei Xinle Sci&Tech Co., Ltd
No.2, Xingye Street, Xinle City, 050700 Shijiazhuang City, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
Establishment Registration Number: 3014498762

Contact Person: Jianxun Tian
Position: Regulatory Affairs Manager
Tel: +86- 311-88581058
Fax: +86- 311-88655819
Email: tianjianxun@hbxinle.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Christina Wu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +8621 2281-5850
Fax: 360 925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Lancet
Common Name: Blood Lancet

Regulatory Information

Classification Name: Single Use Only Blood Lancet with an Integral Sharps Injury Prevention Feature
Classification: II
Product Code: FMK
Regulation Number: 21 CFR 878.4850
Review Panel: General & Plastic Surgery

Indications for Use: It is intended for capillary blood sampling.

Device Description

The propose device, Lancet, which is intended for capillary blood sampling. The safety protection mechanism is to prevent the reuse of products and protection against needle stick injury. The proposed devices are provided sterile, single use.

The proposed devices are divided into several models. In addition, the proposed devices are available in different specifications of needle gauge (21G, 28G and 30G) to allow to collect capillary blood sample.

5. Identification of Predicate Devices

510(k) Number: K192666
Product Name: Promisemed Blood Lancet, VeriFine Safety Lancet, VeriFine Mini-Safety Lancet
Regulation number: 21 CFR 878.4850
Product Code: FMK

6. Comparison of Technological Characteristics

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K192666	Remark
Product Code	FMK	FMK	Same
Regulation Number	21 CFR 878.4850	21 CFR 878.4850	
Class	II	II	
Prescription/ Over-The-Counter Use	Over-The-Counter Use	Over-The-Counter Use	Same
Indications for Use	It is intended for capillary blood sampling.	It is intended for capillary blood sampling.	Same
Safety Protection Features	Yes	Yes	Same
Operate mode	Manual	Manual	Same

Single Use	Yes	Yes	Same
Configuration	Shell, Trigger, Needle Connector, Back Cap, Spring, Needle, Protective Cap	Shell, Trigger, Needle Connector, Back Cap, Spring, Needle, Protective Cap	Same
Materials of Parts in Contact with Human Body	Shell (PP) Trigger, Protective Cap (PS) Needle Connector, Back Cap (PE) Needle (Stainless Steel)	Needle (Stainless Steel) Other Parts: Plastics Materials	Similar Analysis 1
Label/Labeling	Conform with 21 CFR Part 801	Conform with 21 CFR Part 801	Same
Needle Gauge	21G, 28G, 30G	21G, 23G, 26G, 28G, 30G	Similar Analysis 2
Performance	Comply with ISO 9626 ISO 7864	Comply with ISO 9626 ISO 7864	Same
Biocompatibility			
In Vitro Cytotoxicity	Conform with ISO 10993 Standards	Conform with ISO 10993 Standards	Same
Skin Sensitization			
Intracutaneous Reactivity			
Acute Systemic Toxicity			
Hemolytic Properties			
Pyrogen Test			
Sterilization			
Method	Radiation Sterilization	Radiation Sterilization	Same
SAL	10^{-6}	10^{-6}	
Endotoxin Limit	20 EU per device	20 EU per device	

Analysis 1 –Materials of Parts in Contact with Human Body

Some parts' materials of proposed device maybe are different with predicate device. However, the biocompatibility test for proposed device has been tested and the results comply with the requirements of ISO 10993.

Analysis 2- Needle Gauge

The needle gauge between the proposed device and predicate device is different. The needle gauge of predicate device covers the scope of needle gauge of proposed device.

7. Non-Clinical Test Summary

Non clinical tests were conducted to verify that the proposed devices met all design specifications as was Substantially Equivalent (SE) to the predicate device. The tests performed on the relevant device configurations include:

Biocompatibility test

Biocompatibility tests was conducted on the lancet, include in vitro cytotoxicity test (ISO 10993-5), skin sensitization Test (ISO 10993-10), Intracutaneous Reactivity Test (ISO 10993-10), Acute Toxicity Test (ISO 10993-11), Pyrogen Test (ISO 10993-11) and Hemolysis Test (ASTM F756-17).

Simulated Clinical Use

A simulated clinical use study was performed on 600 device samples each for the 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 requirements.

Bench test

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.

- Limits of Acidity or Alkalinity Test
- Limits for Extractable Metals Test
- Surface Finish and Visual Appearance Test
- Dimensions Test Record
- Test Records for Resistance to Corrosion
- Penetration Force Test
- Puncture Depth Test
- Bond Between Needle Connector and Needle Test

The test results demonstrated that the proposed device complies with the following standards and guidance.

- ISO 7864:2016 Sterile hypodermic needles for single use - Requirements and test methods
- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices -

Requirements and test methods

- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO11137-2:2006, Sterilization of healthcare products-Radiation-Part2: Establishing the sterilization dose
- ISO 23908:2011 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- ASTM F756-17: Standard Practice for Assessment of Hemolytic Properties of Materials
- ASTM D4169-16: Standard Practice for Performance Testing of Shipping Containers and Systems
- USP <85> Bacterial Endotoxins Test
- USP-NF<71> Sterility Tests
- USP-NF<151> Pyrogen Test
- Simulated Use Study Sharps Injury Prevention Feature FDA Guidance, Guidance for Industry and FDA Staff: Medical Device with Sharps Injury Prevention Feature, issued on August 9, 2005
- Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process" dated April 23, 2020

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.