October 28, 2024

Ningbo Caremed Medical Products Co., Ltd.
℅ Kyra Kang
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd
Room 1308, Baohua International Plaza,
West Guangzhong Road 555, Jingan District
Shanghai,
China

Re: K242622
Trade/Device Name: Sterile Lancets for Single Use
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL
Dated: August 27, 2024
Received: September 3, 2024

Dear Kyra Kang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.10.28 15:36:30 -04'00'

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)*
K242622

Device Name
Sterile Lancets for Single Use

Indications for Use *(Describe)*
Lancet 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary

I. Submitter

Ningbo Caremed Medical Products Co., Ltd.

No.79 Jiutang Road, Hangzhou Bay New Zone, Ningbo, China

Preparation date: October 24, 2024.

Contact person: Ms. Cen Wei

Position: General Manager

Tel.: +86-574-58582551

E-mail: Wei-cen@caremed-nb.com

Submission Correspondent

Ms. Kyra Kang

Landlink Healthcare Technology (Shanghai) Co., Ltd.

E-mail: kyra.kang@landlink-health.com

II. Proposed Device

Device Trade Name:	Sterile Lancets for Single Use
Common name:	Blood Lancets
Regulation Number:	21 CFR 878.4850
Regulatory Class:	Class II
Product code:	QRK
Review Panel:	General & Plastic Surgery

III. Predicate Devices

510(k) Number:	K220475
Trade name:	Lancet (I, II, III, V, VI); Lancing device (HH-X-T, HH-XIII-T, HH-XV-T, HHXVI-T, HH-XVII-T, HH-XVIII-T, HH-XIX, HH-XXI-T, HH-XXII-T, HHXXIII-T, HH-XXIV-T)
Common name:	Blood Lancets
Classification:	Class II
Product Code:	QRL,QRK
Manufacturer	Tianjin Huahong Technology Co., Ltd.

IV. Device description

The Sterile Lancets for Single Use is intended for capillary blood sampling.

The Sterile Lancets for Single Use is composed two components: needle and needle holder. Needle holder is plastic part that enclosed the needle. The sterile barrier is the needle holder and sterilized to a SAL of 10-6 by radiation sterilization. It is intended for single use only.

The lancet is together with a lancing device to puncture the skin to obtain a drop of capillary blood from fingertip or from alternative sites.

The shelf-life of the product is 5 years.

V. Indication for use

The Sterile Lancets for Single Use is intended for capillary blood sampling.

VI. Comparison of technological characteristics with the predicate devices

Table 5.2-1 General Comparison of Sterile Lancets for Single Use

Characteristics	**Proposed device**	**Predicate device (K220475)**	**Discussion**
Manufacturer	Ningbo Caremed Medical Products Co., Ltd.	Tianjin Huahong Technology Co., Ltd.	/
Product name	Sterile Lancets for Single Use	Lancet	/
Product code	QRK	QRL,QRK	Same
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 Sterile Lancets for Single Use is intended for capillary blood sampling.	It is intended for capillary blood sampling	Same
Applicable	Healthcare professional or	Healthcare professional or	Same

user	lay person	lay person	
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 Color master batch) forming a body and cap, encapsulating the stainless steel needles.	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.	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 needle for use.	The Lancet comprises a stainless steel needle encapsulated with a plastic body and cap, the cap is twisted off to expose the needle for use.	Same
Needle length range	3.2±0.3mm	3.2±0.3mm（Model：IA、IB、 IC、ID、IE、IK、IL、IM、IIA、 IIB、III、VI） 2.1±0.3mm（Model：V）	Same
Gauge range	18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G, 32G, 33G, 34G	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）	Similar 1

		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）	
Shelf-life	5 years	5 years	Same
Materials of parts in contact with human body	Needle: Stainless steel Needle holder (Main body & Protective cap): PE&Color master batch	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) and calcium powder.	Similar 2
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

Similar 1- Gauge range

The gauge range of proposed device can be covered by predicate device, all performance has been tested, this difference will not raise any issues in safety and effectiveness

Similar 2 – Materials of parts in contact with human body

Biocompatibility of the Sterile Lancets for Single Use was evaluated in accordance with the FDA guidance “Use of International Standard ISO 10993-1”, this difference will not raise any issues in safety and effectiveness.

VII. Non-Clinical Testing

Performance Testing

Performance testing is conducted according to Inspection Specification， the test sample has undergone accelerated aging for 5.5 years.

Tested the following projects：Appearance，Dimension，Firmness of needle and main body，Puncture Performance，Matching，Launch Performance，Bacterial endotoxin，Sterilization

Biocompatibility testing

Biocompatibility of the Sterile Lancets for Single Use was evaluated in accordance with the FDA guidance “Use of International Standard ISO 10993-1” The following testing was conducted:

- Cytotoxicity ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- Sensitization ISO 10993-10:2021 Biological evaluation of medical devices − Part 10: Tests for skin sensitization
- Irritation ISO 10993-11:2017 Biological evaluation of medical devices − Part 11: Tests for systemic toxicity
- Acute Systemic ISO 10993-23:2021 Biological evaluation of medical devices − Part 23: Tests for irritation
- Pyrogenicity ISO 10993-11:2017 Biological evaluation of medical devices − Part 11: Tests for systemic toxicity

Sterility and Shelf -life

After five years of accelerated aging, the product has passed all tests, so it can be guaranteed that the product can be used normally within five years, and the shelf life can reach five years

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.