August 20, 2024

Ningbo Caremed Medical Products Co. Ltd.
℅ Evan Hu
Technical and Regulatory Director
Shanghai Mind-link Consulting Co., Ltd.
377 Tianzhu Road, Jiading
Shanghai, 201801, China

Re: K241848
Trade/Device Name: MedtFine Safety Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: June 13, 2024
Received: June 27, 2024

Dear Evan Hu:

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.

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: 2024.08.20 13:09:43 -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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241848

Device Name

MedtFine Safety Lancet

Indications for Use *(Describe)*

The safety 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.

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510(k) Summary

1. **Preparation date: Jun 12, 2024**

2. **Submitter**

Manufacturer: Ningbo Caremed Medical Products Co. Ltd.
Address: No.79 Jiutang Road, South Side Hangzhou Bay New Zone, Ningbo 315336, China.
Contact person: Cen Wei, General Manager,
+86057458582551, wei-cen@caremed-nb.com
Submission correspondent: Evan Hu, Technical and Regulatory Director,
+86-18616124827, evan.ww.hu@outlook.com

3. **Device**

Trade name: MedtFine Safety Lancet
Common name: Blood Lancet
Regulation Name: Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature
Regulation: 21 CFR § 878.4850
Product code: FMK
Classification: Class II
Review Pannel: General & Plastic Surgery

4. **Predicate device**

Predicate device: K220370
Trade name: Safety Lancet (Model: XIII, XVII, XXI, XXII, XXIII, XXIV, XXV, XXVI)
Common name: Blood Lancet
Regulation Name: Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature
Regulation: 21 CFR § 878.4850
Product code: FMK
Classification: Class II
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5. **Device description**

Sterile safety lancet consists of outer shell, middle sleeve, needle holder, spring, upper shell, back cover, small cover, needle. The sterile part of the safety lancet is the needle tip. The sterile barrier is the needle holder and sterilized to a SAL of 10-6 by radiation

sterilization. It is intended for single use and single person use only. The shelf-life of the product is 5 years. The device is for medical professionals and lay person use as an OTC use.

Table 1. Device specifications

NO.	Gauge	Needle exposure length (±0.3mm)	Color
1	18G	1.8	Orange
2	18G	2.2	Rose red
3	18G Blade	3.0	Deep green
4	21G	2.2	Grass green
5	21G	2.4	Light Blue
6	23G	2.2	Deep blue
7	26G	1.8	Yellow
8	28G	1.8	Lake blue
9	30G	1.6	Pink
10	32G	1.6	Purple

6. Indications for use/Intended use

The safety lancet is intended for capillary blood sampling.

7. Comparison of technological characters between proposed and predicate devices

Table 2. Characters comparison

Element of Comparison	MedtFine Safety Lancet	Safety Lancet (K220370)	Comment
Product Code	FMK	FMK	Same
Indication for Use	The safety lancet is intended for capillary blood sampling.	The safety lancet is intended for capillary blood sampling.	Same
OTC and Rx Use	OTC use	OTC use	Same

Element of Comparison	MedtFine Safety Lancet	Safety Lancet (K220370)	Comment
Specifications	Needle: 18G, 18G blade, 21G, 23G, 16G, 28G, 30G, 32G House Type: XXV (below graph) 	Needle: 18G, 18G blade, 21G, 23G, 16G, 28G, 30G, 32G House Type: XIII, XVII, XXI, XXII, XXIII, XXIV, XXV (below graph), XXVI 	Same, within range.
Safety protection features	Yes	Yes	Same
Reuse durability	Single use for single person	Single use for single person	Same
User environments	Home, clinical	Home, clinical	Same
Components and materials	Outer shell: PP Middle sleeve: ABS Needle holder: PE Spring: carbon steel Upper Shell: PE Back cover: PE Small cover: PP Needle: Stainless Steel	Needle core (contain Needle): PE, PP Calcium powder (main ingredient: calcium carbonate) stainless steel (needle) silicone oil (needle) Housing, Button, Bottom, Protective cap, Small lid, Depth adjuster ring: ABS, PS	#1
Sterilization	Radiation SAL=10^{-6}	Radiation SAL=10^{-6}	Same
Shelf life	5 years	5 years	Same
Activation force	4~7N	4~15N	Same, within range.
Puncture force	18~26G: 0.6~1.3N <2N 28~32G: 0.38~0.71N <1N	18~26G: 0.7~1.4N <2N 28~32G: 0.7~0.9N <1N	Same, meet requirements
Puncture depth (needle exposure length)	18~32G: 1.6~2.2mm 18G blade: 3.0mm	18~32G: 1.6~2.2mm 18G blade: 3.0mm	Same
Biocompatibility	Meet requirements of ISO 10993 serial standards	Meet requirements of ISO 10993 serial standards	Same

Comments:

#1: The proposed and predicate devices used different materials for manufacturing. The device structures kept the same. The performance testing and biocompatibility testing results demonstrated the proposed device met the requirements of various standards

8. Non-clinical testing

PERFORMANCE TESTING
The following tests were performed per ISO 9626:2016 and internal requirements to demonstrate substantial equivalence:

- Appearance
- Needle size
- Firmness of needle and plastic handle
- Puncture force
- Safety performance
- Limits for acidity or alkalinity
- Resistance to corrosion

Besides, the following tests were performed to determine the safe usage of devices.

- Sharps injury protection per ISO 23908
- Simulated clinical use study per FDA Guidance: Medical Devices with Sharps Injury Prevention Features

BIOCOMPATIBILITY TESTING:
The proposed device was tested in compliance 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”, as the Externally Communicating Device, Blood Path Indirect, Limited Contact (< 24hrs).
The items listed below underwent testing in accordance with ISO 10993-1.

- Cytotoxicity
- Intracutaneous Reactivity
- Sensitization
- Systemic toxicity
- Hemolysis
- Pyrogen
- Endotoxin

STERILE, PACKAGE AND SHELF-LIFE:
The sterilization process of the proposed device has been validated in compliance with ISO 11137-2:2013.
The Shelf-Life validation study was conducted under accelerated aging conditions in compliance with ASTM F1980-16 to verify the claimed shelf-life of 5 years.

Package integrity testing under simulated shipping conditions was conducted to satisfy the requirements in ASTM F4169-22. All packaging was deemed acceptable for protection of product and sterility maintenance.
Sterile barrier testing was conducted in compliance with the following FDA recognized consensus standards.

- Cap removal force: ASTM F88/F88-15
- Dye penetration: ASTM F1929-23.
- Sterility: USP <71>

9. Clinical testing

Not applicable for this submission**.**

10. Conclusion

The differences between the predicate and the proposed device do not raise any new or different questions of safety or effectiveness. The proposed device is substantially equivalent to the predicate device with respect to indications for use and technological characteristics.