August 15, 2024

Medifun Corporation
% Mandy Lin
Regulatory Affairs Consultant
Voler Biotech Consulting CO., Ltd
6F.-17, No. 14, Ln. 609, Sec. 5, Chongxin Rd., Sanchong Dist
New Taipei City, 241407
Taiwan

Re: K241750
Trade/Device Name: Medifun Safety Lancet (MSL1 series)
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: June 18, 2024
Received: June 18, 2024

Dear Mandy Lin:

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: 2024.08.15 07:57:15 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and
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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.

510(k) Number *(if known)*
K241750

Device Name
Medifun Safety Lancet (MSL1 series)

Indications for Use *(Describe)*
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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

1. Submission Information

Submitter: Medifun Corporation
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Taichung City 408, Taiwan (R.O.C.)
Submitter contact: Aaron Chen
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2. Device Name and Classification

Product Name:	Medifun Safety Lancet (MSL1 series)
Classification Name:	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature
Common or Usual Name:	Blood lancets
Regulation Number:	21 CFR 878.4850
Product Code:	FMK

3. Predicate Device(s)

Product Name:	Safety Lancet (8 models: XIII, XVII, XXI, XXII, XXIII, XXIV, XXV, XXVI) (K220370)
Common or Usual Name:	Blood lancets
Regulation Number:	21 CFR 878.4850
Product Code:	FMK

4. Device Description

The Medifun Safety Lancet (MSL1 series) is designed to obtain capillary blood samples from the fingertip.

The intended users include healthcare personnel, patients, and lay persons.

According to the needle and color differences, the safety lancets have 6 models : MSL1-30, MSL1-28, MSL1-26, MSL1-23, MSL1-21, and MSL1-18. The safety lancets consist of the needle seat, main body, release platform, spring, and protective cap.

The sterile part of the safety lancet is the needle tip. The sterile barrier is the needle sleeve and sterilized to a SAL of 10^{-6} by radiation sterilization. It is intended for single use only. The shelf-life of the product is 5 years.

The lancets contain a safety feature. After use, the puncture mechanism retracts,

rendering it unusable for a second time.

5. Indications for Use

Safety lancet is intended for capillary blood sampling.

6. Comparison to the Predicate Device

	Proposed Device	Predicate Device K220370	Differences
Item	Medifun Safety Lancet (MSL1 series)	Safety Lancet (8 models: XIII, XVII, XXI, XXII, XXIII, XXIV, XXV, XXVI)	NA
Classification	2 (21CFR878.4850)	2 (21CFR878.4850)	Same
Product Code	FMK	FMK	Same
Indications for Use	Safety lancet is intended for capillary blood sampling.	The safety lancet is intended for capillary blood sampling.	Same
Safety protection features	Yes	Yes	Same
Reuse durability	Single use	Single use	Same
Sterilization method and SAL	Sterilized by Radiation SAL=10^{-6}	Sterilized by Radiation SAL=10^{-6}	Same
Self-life	5 years	5 years	Same
Materials of parts in contact with human body	Needle: stainless steel Other parts: plastic materials	Needle core (contain Needle): PE, PP, Calcium Powder (main ingredient: calcium carbonate), stainless steel (needle), silicone oil (needle); Housing, Button,	Similar[1]

	Proposed Device	Predicate Device K220370	Differences
Item	Medifun Safety Lancet (MSL1 series)	Safety Lancet (8 models: XIII, XVII, XXI, XXII, XXIII, XXIV, XXV, XXVI)	NA
		Bottom, Protective cap, Small lid, Depth adjuster ring: ABS, PS	

[1] The Medifun safety lancet shares many of the same technological characteristics as the predicate device. The subject device's raw materials may differ from the predicate device. However, all the materials are known biocompatible materials that have been used in lancets or other similar medical devices.

7. Performance Data

Non-clinical tests were performed on the proposed device.

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

Item	Acceptance Criteria	Result
Appearance	Consistent with the drawings. There should be no damage, dirt, or holes and the protective cap must not be pulled open.	Meet the requirement
Dimension	Consistent with the drawings.	Meet the requirement
Firmness	The needle must remain firmly attached to the plastic part of the needle seat.	Meet the requirement
Needle protrusion length	Use calipers to measure and meet the requirements.	Meet the requirement
Launch performance	It must be able to fire smoothly, and there should be no abnormal rebound noise after firing.	Meet the requirement
Puncture force	The needle tip of the needle should have good puncture ability.	Meet the requirement
Disposable	The safety lancet is only allowed to be puncture once, and it becomes invalid and cannot be fired again after	Meet the requirement

	it has been punctured.	
Safety Feature	The downward firing force <2 kg After firing, the needle tip must retract and the needle must not touch the surface of the balloon.	Meet the requirement
Protective cap pull test	It must be possible to smoothly open the protective cap within a full cycle.	Meet the requirement
Structural strength	The combined force between the protective cap of the needle seat and the main body must be greater than 2.5 kg.	Meet the requirement
Drop test	Perform a puncturing test after a fall, it must be able to puncture normally.	Meet the requirement
Compression test	After pressing down the protective cap, it must be able to rebound. There should be no shrinkage or jamming.	Meet the requirement
Resistance to corrosion	The corrosion resistance of the needle of the lancet shall show no evidence of corrosion.	Meet the requirement
Acidity or Alkalinity	The pH value of an extract prepared refers to ISO 9626 Annex A shall be within one pH unit of that of the control fluid.	Meet the requirement
Limits for Extractable Metals	When corrected for the metal content of the control fluid, contain not greater than a combined total of 5 mg/l of lead, tin, zinc and iron. The cadmium content of the extract shall, when corrected for the cadmium content of the control fluid, be lower than 0.1 mg/l.	Meet the requirement

Biocompatibility Testing:

The tests include the following tests:

- *In Vitro* Cytotoxicity
- Skin Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Pyrogenicity

Simulated Clinical Use

A simulated clinical use study was performed on 500 device samples for the Safety Lancet according to FDA Guidance, Guidance for Industry and FDA Staff: Medical Device with Sharps Injury Prevention Feature, issued on August 9, 2005, to evaluate

the safety mechanism of the proposed device. The results demonstrated that the proposed device met the pre-established criteria.

Conclusion

The proposed device has the same indication for use and has similar design features and technological characteristics as the predicate device. Performance testing data demonstrates that the proposed device is as safe and effective as the predicated device. Accordingly, the proposed device is substantially equivalent to the predicate device.