



November 22, 2023

Medifun Corporation
Tyra Chiu
Regulatory Consultant
VOLER Biotech Consulting Co., Ltd.
IF, No 3-1, Ln. 58, Hejiang St., Zhongshan Dist, Taipei, 104 Taiwan

Re: K231797

Trade/Device Name: Medifun Lancing Device, Model No. LD-E1
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL
Dated: August 25, 2023
Received: September 5, 2023

Dear Tyra Chiu:

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,

Mark
Trumbore -S

 Digitally signed by Mark Trumbore -S
Date: 2023.11.22 15:25:01 -05'00'

Mark Trumbore, 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

Indications for Use

510(k) Number (if known)

K231797

Device Name

Medifun Lancing Device, Model No. LD-E1

Indications for Use (Describe)

Medifun Lancing Device, Model No. LD-E1 is a reusable lancing device for the single user. It should be used with the proper sterile lancet for the capillary blood sampling. It could automatically inject the lancet into and retract it from the fingertip to obtain a capillary blood sample for glucose monitoring or other test that require one or two drops of blood. A depth adjustable cap allows the best depth of skin penetration for each individual user. Alternative site testing (palm or forearm) can be performed by installing the clear cap on the lancing device.

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.

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510(k) Summary

Date May 09, 2023

Manufacturer/ Medifun Corporation

510(k) Owner 4F-1, 4F-9, 4F-10, No.99, Jingke S. Rd., Nantun Dist., Taichung City
408, Taiwan (R.O.C.)

Contact Person

Aaron Chen

Device Trade Name Medifun Lancing Device, Model No. LD-E1

Common Name Multiple Use Blood Lancet For Single
Patient Use Only

Classification Name Multiple Use Blood Lancet For Single
Patient Use Only

Device Class II

Classification Panel General & Plastic Surgery

Regelation Number 21 CFR 878.4850

Product Code QRL

Device Description and Technology Characteristics Medifun Lancing Device, Model No. LD-E1 is a mechanical blood lancet holder. It is used with a single use sterile lancet to puncture the skin for collecting capillary whole blood sampled from the fingertip or alternate sites. Medifun Lancing Device LD-E1 can be adjusted for 6 levels of depth. This device is for single user only.

Indications for Use Medifun Lancing Device, Model No. LD-E1 is a reusable lancing device for the single user. It should be used with the proper sterile lancet for the capillary blood sampling. It could automatically inject the lancet into and retract it from the fingertip to obtain a capillary blood sample for glucose monitoring or other test that require one or two drops of blood. A depth adjustable cap allows the best depth of skin penetration for each individual user. Alternative site testing (palm or forearm) can be performed by installing the clear cap on the lancing device.

Predicate Device(s) K221062 RIGHTEST Lancing Device GD500, GE Lancing Device, iGlucose Lancing Device, submitted by Bionime Corporation

Discussion on Performance Data Non-Clinical Tests Non-clinical bench testing was performed to ensure predetermined criteria were met and the special controls were satisfied. This includes mechanical design verification and validation testing in order to ensure the risks were appropriately managed in addition to, verifying that the

device continued to meet the specified requirements. The following non-clinical tests were conducted to evaluate the safety and performance of the subject device and provide evidence to support the verification and validation:

- ISO 10993-5 In vitro Cytotoxicity
- ISO 10993-23 Skin Irritation
- ISO 10993-10 Skin Sensitization
- cleaning validation
- Risk management according to ISO 14971:2019.
- Specification and functional tests

Substantial Equivalence The subject device has same indications for use, technology, and operation principle as well as similar technical characteristics with the predicate device. Verification activities were performed on subject device and all tests were verified to meet the required acceptance criteria. The verification tests demonstrate that the differences in the device do not affect the intended use of the device or raise any unsolved issues. There are no significant differences between subject device and the predicate device(s). We conclude that subject device is substantially equivalent to predicate devices.

Conclusion Based on the information provided in this premarket notification, we believe the proposed Medifun Lancing Device, Model No. LD-E1 and its predicate device are substantially equivalent in their intended use, both devices share similar design and technology characteristics.

Summary of Comparison and Technological Characteristics

	Proposed Device	Predicate Device	Substantial Equivalence Comparison
Device Name	Medifun Lancing Device , Model No. LD-E1	RIGHTEST Lancing Device GD500, GE Lancing Device and iGlucose Lancing Device	-
510(k) #	-	K221062	-
Product code	QRL	QRL	Identical
Classification	Class II	Class II	Identical
Intended Use	Medifun Lancing Device, Model No. LD-E1 is a reusable lancing device for the single user. It should be used with the proper sterile lancet for the capillary blood sampling. It could automatically inject the lancet into and retract it from the fingertip to obtain a capillary blood sample for glucose monitoring or other test that require one or two drops of blood. A depth adjustable cap allows the best depth of	RIGHTEST Lancing Device GD500 is a reusable lancing device for the single user. It should be used with the proper sterile lancet for the capillary blood sampling. It could automatically inject the lancet into and retract it from the fingertip to obtain a capillary blood sample for glucose monitoring or other test that require one or two drops of blood. A depth adjustable cap allows the	Identical

skin penetration for each individual user. Alternative site testing (palm or forearm) can be performed by installing the clear cap on the lancing device.

best depth of skin penetration for each individual user. Alternative site testing (palm or forearm) can be performed by installing the clear cap on the lancing device.

GE Lancing Device is a reusable lancing device for the single user. It should be used with the proper sterile lancet for the capillary blood sampling. It could automatically inject the lancet into and retract it from the fingertip to obtain a capillary blood sample for glucose monitoring or other test that require one or two drops of blood. A depth adjustable cap allows the best depth of skin penetration for each individual user.

Alternative site testing (palm or forearm) can be performed by installing the clear cap on the lancing

		<p>device.</p> <p>iGlucose Lancing Device is a reusable lancing device for the single user. It should be used with the proper sterile lancet for the capillary blood sampling. It could automatically inject the lancet into and retract it from the fingertip to obtain a capillary blood sample for glucose monitoring or other test that require one or two drops of blood. A depth adjustable cap allows the best depth of skin penetration for each individual user.</p>	
OTC/ Prescription Use	OTC	OTC	Identical
Operation Principle	Mechanical puncture device to obtain micro blood samples	Mechanical puncture device to obtain micro blood samples	Identical
Materials of construction	ABS plastic, Polyoxymethylene, SUS304 stainless-steel springs	-	Different
Depth Adjustment	6 different depths, 0.5mm-1.7 mm	7 different depths, 0.5 mm- 1.7 mm.	Similar

Loading and Firing	Mechanical, Spring-driven	Mechanical, Spring-driven	Identical
Sharps Injury Prevention	Lancet retract after use	Lancet retract after use	Identical
Device Sterility	Non-sterile	Non-sterile	Identical
Number of Use	multiple use for single patient only	multiple use for single patient only	Identical
Biocompatibility	ISO 10993-1, ISO 10993-5, ISO 10993-10 ISO 10993-23	ISO 10993-1, ISO 10993-5, ISO 10993-10	Identical