11/15/2022

Tianjin Rilifine Medical Device Co., Ltd.
Qiusheng Jiang
Manager
No 32, Jingguan Road, Yixingbu, Beichen District
Tianjin, 300402
China

Re: K222055
Trade/Device Name: Disposable Sterile Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: October 20, 2022
Received: October 21, 2022

Dear Qiusheng Jiang:

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,

Jessica Carr -S

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)*
K222055

Device Name
Disposable Sterile 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.

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K222055

510(K) SUMMARY

(In accordance with 21 CFR 807.92)

1.0 Submitter's Information

Name:	Tianjin Rilifine Medical Device Co., Ltd.
Address:	No 32, Jingguan Road, Yixingbu, Beichen District Tianjin, 300402, CHINA
Phone Number:	86-22-23233999
Contact:	Mr. Qiusheng Jiang
Date of Preparation:	July 5, 2022

2.0 Device Information

Device Name:	Disposable Sterile Lancet
Common Name:	Rilifine Safety Lancet
Classification Name:	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature

3.0 Classification

Product Code:	FMK
Regulation Number:	21 CFR 878.4850
Classification:	II
Review Panel:	General & Plastic Surgery

4.0 Predicate Device Information

Manufacturer:	Promisemed Hangzhou Meditech Co., Ltd.
Device:	Promisemed Blood Lancet, VeriFine Safety Lancet, VeriFine Mini-Safety Lancet
510(k) Number:	K192666
Classification	I
Product Code	FMK

5.0 Intended Use

It is intended for capillary blood sampling.

6.0 Device Description

Disposable Sterile Lancet is Class II Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature bearing the product code FMK (21CFR878.4850).

The lancet is for single use, disposable sterile devices, which is designed to collect capillary blood samples.
The intended users include healthcare personnel, patients and lay users.
The Disposable Sterile Lancet consist of protective cap, housing, bottom, fire button, connection ring, springs (ejection spring and fire spring), and core of lancet (including needle).

The sterile part of the 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.

7.0 Comparison of Technological Characteristics with Predicate Device

The following table is the summary of the technological characteristics, biocompatibility of the proposed subject device and predicate device.

Item	**Subject Device**	**Predicate Device (**K192666**)**	**Comparison Result**
Manufacturer	Tianjin Rilifine Medical Device Co., Ltd.	Promisemed Hangzhou Meditech Co., Ltd.	--
510K number	--	K192666	--
Product name	Disposable Sterile Lancet	Promisemed Blood Lancet, VeriFine Safety Lancet, VeriFine Mini-Safety Lancet	--
Classification	II	I	See Note 1
Product Code	FMK	FMK	Same
Regulation Number	21 CFR 878.4850	21 CFR 878.4800	See Note 1
Intended Use	It is intended for capillary blood sampling.	It is intended for capillary blood sampling.	Same
Single Use	Single Use	Single Use	Same
Feature	Safety protection	Safety protection	Same
Principles of operation	Pressure activated	Pressure activated	Same
Sterilzation method and SAL	Sterilized by radiation SAL=10^{-6}	Sterilized by radiation SAL=10^{-6}	Same
Shelf life	5 years	5 years	Same

Item		Subject Device	Predicate Device (K192666)	Comparison Result
Materials of parts in contact with human body		Needle: stainless steel Other parts: plastic materials, such as ABS, PP etc.	Needle: stainless steel Other parts: plastic materials	Similar, See note 2
Needle length		0.7mm, 0.8mm, 0.9mm, 1.0mm, 1.1mm, 1.2mm, 1.3mm, 1.4mm, 1.5mm, 1.6mm, 1.7mm, 1.8mm, 1.9mm, 2.0mm, 2.1mm, 2.2mm, 2.3mm, 2.4mm, 2.5mm, 2.6mm, 2.7mm, 2.8mm, 2.9mm, and 3.0mm	1.2mm, 1.4mm, 1.6mm, 1.8mm, 2.0mm, 2.2mm, 2.4mm, 2.6mm, 2.8mm	Similar, see note 3
Bio-compatibility	Primary Skin Irritation	Under the condition of study not an irritant	Under the condition of study not an irritant	Same
	Dermal Sensitization	Under the conditions of the study not a sensitizer	Under the conditions of the study not a sensitizer	Same
	Cytotoxicity	Under the conditions of the study, no cytotoxic potential	Under the conditions of the study, no cytotoxic potential	Same

Note 1: The classification and regulation number are different because FDA issued the final order about reclassification of Blood Lancet Nov 22, 2021.

Note 2: The raw materials of the proposed devices may be different from the predicate device. However, all the materials are known biocompatible materials that have been used in lancets or other similar medical devices.

Note 3: The length for the proposed device is wider than the predicate device K192666. Concerning the differences to the predicate devices, testing is done to the representative length of the proposed device, which are the extreme conditions for the device, that is length of 0.7mm (to review whether the length is long enough to get the required penetration), and length of 3.0mm (to review whether the length is too long to affect the retraction of the needle-tip after the product is activated). And based on the testing report, it is showed that the performance and safety feature for the products are not affected.

There are no significant differences between the two products and are identical in terms of intended use, design and technological characteristics.

8.0 Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- ISO 11137-1 First edition 2006-04-15, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2018)]

- ISO 11137-2 Third edition 2013-06-01, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-23 First edition 2021-01,Biological evaluation of medical devices - Part 23: Tests for irritation

Performance testing verified 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 as follows:

Items		**Acceptance Criteria**	**Results**
Appearance	Product Appearance	No obvious foreign body, fracture, unformed defects etc.	Meet the requirements
	Needle-tip	No obvious burrs, curved hooks, oil stains etc. Lancet should be well assembled, no obvious dislocation at the fitting of the shell	Meet the requirements
Dimensions	Diameter of needle core	Product dimensions shall be consistent to the drawings	Meet the requirements
	Length of exposed needle-tip	The length of exposed needle-tip shall be consistent to the drawings.	Meet the requirements
Performance	Puncture Depth	Using A4 printing paper for simulated testing and meet the requirements	Meet the requirements
	Launch performance	The operation of Fire should be smooth, after launching,	Meet the requirements

		the tip of the needle should be automatically retracted into the housing	
	Firmness	Needle should connect firmly with plastic handle	Meet the requirements
Sterility		The sterility for the device shall be at SAL of 10^{-6}	Meet the requirements

Biocompatibility testing as per ISO 10993 standards:

Item	Subject device	Result
Cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	Pass
Irritation	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	Pass
Sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	Pass
Acute systemic toxicity	Under the condition of this study, not an acute systemic cytotoxic potential	Pass
Pyrogenicity	Under the condition of this study, no pyrogenicity reaction	Pass

9.0 Clinical Test

No clinical study is included in this submission.

10. Comparison to the Predicate Device and Conclusion

The conclusion drawn from the nonclinical tests demonstrate that the subject device Disposable Sterile Lancet has the same indication for use and has similar design features and technological characteristic as the predicate device, and the proposed device is as safe, as effective and performs as well as the legally marketed predicate device K192666.