11/21/2022

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

Re: K222246
Trade/Device Name: Disposable Sterile Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood lancets
Regulatory Class: Class II
Product Code: QRL, QRK
Dated: September 26, 2022
Received: September 27, 2022

Dear Mr. 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)*
K222246

Device Name
Disposable Sterile Lancet; lancing device

Indications for Use *(Describe)*
Disposable Sterile Lancet:
The lancet is intended for capillary blood sampling.

Lancing Device:
The Lancing Device is used with lancets to draw capillary blood from the fingertip, for testing utilizing small amounts of blood. The Lancing Device is single patient use only and should not be shared with anyone else, even a family member.

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

(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<br>Tianjin, 300402, CHINA |
| Phone Number: | 86-22-23233999 |
| Primary Submitter: | Mr. Qiusheng Jiang |
| Title | Co-founder and Manager |
| Email: | henry@rilifine.com |
| Secondary Submitter: | Ms. Belinda Wang |
| Title: | Regulatory manager |
| Email: | belindaw@126.com |
| Date of Preparation: | Nov 17, 2022 |

## 2.0 Device Information

| | |
|---|---|
| Device Name: | Disposable Sterile Lancet; Lancing device |
| Common Name: | Rilifine Blood Lancet, lancing device |
| Classification Name: | Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature<br>Multiple Use Blood Lancet For Single Patient Use Only |

## 3.0 Classification

| | |
|---|---|
| Product Code: | QRK, QRL |
| Regulation Number: | 21 CFR 878.4850 |
| Classification: | II |
| Review Panel: | General & Plastic Surgery |

## 4.0 Predicate Device Information

| | |
|---|---|
| Manufacturer: | Tianjin Huahong Technology Co., Ltd. |
| Device: | Lancet, lancing device |
| 510(k) Number: | K220475 |
| Classification | II |
| Product Code | QRL, QRK |

## 5.0 Intended Use

Disposable Sterile Lancet:
The lancet is intended for capillary blood sampling-.

Lancing Device:
The Lancing Device is used with lancets to draw capillary blood from the fingertip, for testing utilizing small amounts of blood. The Lancing Device is single patient use only and should not be shared with anyone else, even a family member.

## 6.0 Device Description

Disposable Sterile Lancet is Class II Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature bearing the product code QRK (21CFR 878.4850), and The Disposable Sterile Lancet and lancing device is Class II Multiple Use Blood Lancet For Single Patient Use Only bearing the product code QRL (21CFR878.4850).

The lancet is for single use, disposable sterile devices, which is designed to collect capillary blood samples. And the lancing device is intended for capillary blood sampling with Disposable Sterile Lancet. The lancet can be used independently, or used together with lancing device.

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

The lancet is provided sterile. 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 lancet 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 (K220475) | Comparison Result |
|---|---|---|---|
| Manufacturer | Tianjin Rilifine Medical Device Co., Ltd. | Tianjin Huahong Technology Co., Ltd. | -- |
| 510K number | -- | K220475 | -- |
| Product name | Disposable Sterile Lancet Lancing device | Lancet, Lancing Device | -- |
| Classification | II | II | Same |
| Product Code | QRK, QRL | QRK, QRL | Same |
| Regulation Number | 21 CFR 878.4850 | 21 CFR 878.4850 | Same |

| Item | | Subject Device | Predicate Device (K220475) | Comparison Result |
|---|---|---|---|---|
| Intended Use | | Disposable Sterile Lancet: The lancet is intended for capillary blood sampling.<br>Lancing Device:<br>The Lancing Device is used with lancets to draw capillary blood from the fingertip, for testing utilizing small amounts of blood. The Lancing Device is single patient use only and should not be shared with anyone else, even a family member. | Lancet:<br>Lancet is intended for capillary blood sampling.<br><br>Lancing device:<br>The lancing device is used with lancet to draw capillary blood from fingertip, for testing utilizing small amounts of blood. The lancing device is intended to be used by a single patient and should not be shared. | Same |
| Single Use | | The disposable sterile lancet is single Use, and the lancing device is reusable, but single patient use only | The disposable sterile lancet is single Use, and the lancing device is reusable, single patient use only | Same |
| technical specifica-tions | Needle gauge | 21G (0.82±0.01mm)<br>23G (0.64±0.01mm)<br>26G (0.46±0.01mm)<br>28G (0.36±0.01mm)<br>30G (0.31±0.01mm)<br>31G (0.26±0.01mm)<br>32G (0.24±0.01mm)<br>33G (0.21±0.01mm) | 16G (1.50±0.02mm)<br>18G (0.20±0.01mm)<br>19G (1.07±0.01mm)<br>20G (0.91±0.01mm)<br>21G (0.82±0.01mm)<br>22G (0.72±0.01mm)<br>23G (0.64±0.01mm)<br>24G (0.57±0.01mm)<br>25G (0.51±0.01mm)<br>26G (0.46±0.01mm)<br>27G (0.41±0.01mm)<br>28G (0.36±0.01mm)<br>29G (0.34±0.01mm)<br>30G (0.31±0.01mm)<br>31G (0.26±0.01mm)<br>32G (0.24±0.01mm)<br>33G (0.21±0.01mm)<br>34G (0.19±0.01mm) | Similar, See note 1 |
| | Exposed needle length | Normally the length of exposed needle tip is 3.2±0.3mm. | 3.2±0.3mm (Model: IA, IB, IC, ID, IE, IK, IL, IM, IIA, IIB, III, VI) | |

| Item | | Subject Device | Predicate Device (K220475) | Comparison Result |
|---|---|---|---|---|
| | | Which can also vary per customer requirements from 0.7mm to 3.5mm (±0.3mm). | | |
| | Puncture Force | 17-20G≤4N<br>21-25G≤1.5N<br>26-38G≤1N | The needle-tip of the needle should have good puncture ability. | |
| Principles of operation | | Pressure activated or manual | Pressure activated or manual | Same |
| Sterilization method and SAL | | The disposable sterile lancet is sterilized by radiation<br>SAL=$10^{-6}$ | Sterilized by radiation<br>SAL=$10^{-6}$ | Same |
| Shelf life | | The disposable sterile lancet is 5 years | 5 years | Same |
| Materials of parts in contact with human body | | Needle: stainless steel<br>Other parts: plastic materials, such as PE etc. | 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, See note 2 |
| Biocompatibility | | Conforms to the requirements of ISO 10993 series standards. | Conforms to the requirements of ISO 10993 series standards. | Same |

Note 1: The needle gauge, and Puncture Force of the subject device is not complete same with predicate device, but the needle gauge for the subject device is within the scope of the subject device and have the same specification with the predicate device. And performance testing showed that the subject devices comply with the specification and is similar to that of the predicate device, and no concerns caused related to the device safety and effectiveness, and the product can be guaranteed to be safe and effective.

Note 2: The component and material of proposed devices is different from the predicate devices. However, all the materials are known biocompatible materials that have been used in lancets or other similar medical devices, and the biocompatibility testing showed that the subject device is biocompatible.

There are no other significant differences between the two products in terms of 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 Force | 17-20G≤4N<br>21-25G≤1.5N | Meet the requirements |

| | | | |
|---|---|---|---|
| | | 26-38G≤1N | |
| | 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 conditions of the study, the subject device is no acute systemic toxicity | Pass |
| Pyrogen | Under the conditions of the study, the subject device is no pytogenicity 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 K220475.