August 17, 2022

Suzhou Kyuan Medical Apparatus Co., Ltd.
Shi Ye
Manager
Beiqiao Town
Suzhou, Jiangsu
China

Re: K220387
Trade/Device Name: Disposable Blood Lancets
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL, QRK
Dated: July 18, 2022
Received: July 18, 2022

Dear Shi Ye:

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,

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)*
K220387

Device Name
Disposable Blood Lancets

Indications for Use *(Describe)*
The product is intended to be used in a hospital or at home to obtain capillary blood samples from the fingertip for tests using small amounts of blood. The lancet is intended to be assembled with a lancing device, such that once the lancing device is launched, the needle of the lancet can prick the skin.

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# K220387 510(k) summary

## I Submitter

Device submitter: Suzhou Kyuan Medical Apparatus Co., Ltd.
Beiqiao Town, Suzhou City, P.R.China

Contact person: Shi Ye
General Manager
Phone: +86-512 65995113
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Email: shi.ye@medi-kyuan.com

510(k) number: K220387

Date: 08/17/2022

## II Device

Trade Name of Device: Disposable Blood Lancets
Common Name: Blood Lancets
Regulation Number: 21 CFR 878.4850
Regulation Name:
Single Use Only Blood Lancet without an Integral Sharps Injury Prevention Feature
Regulatory Class: II
Product code: QRK, QRL
Review Panel: General & Plastic Surgery

## III Predicate Devices

| | |
|---|---|
| Trade name: | Promisemed Blood Lancet (Used as predicted device)<br>VeriFine Safety Lancet<br>VeriFine Mini-Safety Lancet |
| Common name: | Blood Lancets |
| Classification: | Class I, Lancet, Blood, 21CFR 878.4800 |
| Product Code: | FMK |
| Premarket Notification: | K192666 |
| Manufacturer: | Promisemed Hangzhou Meditech Co., Ltd. |

## IV Device description

The Disposable Blood Lancets consists of a needle, a body and a cap. The models of the Disposable Blood Lancets are 18G; 21G; 23G; 26G; 28G; 30G; 32G; 33G.

Disposable Blood Lancets are used to collect blood samples for hospital clinic test. It is sterilized by Irradiation and is a single-use product.

**V Indications for use**

The product is intended to be used in a hospital or at home to obtain capillary blood samples from the fingertip for tests using small amounts of blood. The lancet is intended to be assembled with a lancing device, such that once the lancing device is launched, the needle of the lancet can prick the skin.

**VI Comparison of technological characteristics with the predicate devices**

The Disposable Blood Lancets have the same intended use, technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices. The differences between the Disposable Blood Lancets and predicate devices do not alter suitability of the proposed device for its intended use.

| Device feature | Subject Device 1 (Disposable Blood Lancets) | Predicate Device K192666 (Promisemed Blood Lancet) | Comment |
|---|---|---|---|
| Indications for use | The product is intended to be used in a hospital or at home to obtain capillary blood samples from the fingertip for tests using small amounts of blood. The lancet is intended to be assembled with a lancing device, such that once the lancing device is launched, the needle of the lancet can prick the skin. | It is intended for capillary blood sampling. | Similar<br>Comment 1 |
| Product code | QRK, QRL | FMK | Different<br>Comment 1 |
| Reuse durability | Single use | Single use | Equivalent |
| Sterilization | Irradiation | Not available | Different |

| Device feature | Subject Device 1 (Disposable Blood Lancets) | Predicate Device K192666 (Promisemed Blood Lancet) | Comment |
|---|---|---|---|
| | | | Comment 2 |
| Principle of Operation | The Disposable Blood Lancets comprises a stainless steel needle encapsulated with a plastic body and cap, the cap is twisted off to expose the needle for use. | The Promisemed Blood Lancet comprises a stainless steel needle encapsulated with a plastic body and cap, the cap is twisted off to expose the needle for use. | Equivalent |
| Manufacturing | Stainless steel needle is fed into an injection molding machine to over-mold plastic material (polyethylene) forming a body and cap, encapsulating the stainless steel needles. Terminal sterilization process is performed to ensure sterility of an entire product. | For the Promisemed Blood Lancet, stainless steel needle is fed into an injection molding machine to over-mold plastic material (polyethylene) forming a body and cap, encapsulating the stainless steel needles. Terminal sterilization process is performed to ensure sterility of an entire product. | Equivalent |
| Model and Specification | 18G; 21G; 23G; 26G; 28G; 30G; 32G; 33G | BL-30 (30G)<br>BL-28 (28G)<br>(Information gathered from Promisemed Hangzhou Meditech Co., Ltd. official website) | Different Comment 3 |
| Penetration Depth | 3.2mm±0.2 | 3mm<br>(Information gathered from Promisemed Hangzhou Meditech Co., Ltd. official website) | |
| Materials of parts in contact with human body | Lancet needle: stainless steel;<br>Body and cap: PE | Lancet needle: stainless steel;<br>Body and cap: PE | Equivalent |

**Discussion:**

Comment 1

The subject device and the predicate device have the same intended use, to puncture the skin to obtain drops of blood for diagnostic purposes. While the Disposable Blood Lancets have no sharp's prevention features and without the intended use of protecting the user from a needlestick injury. This difference does not affect the clinical safety of the subject device.

Comment 2

The sterilization method of predicate device is not available. However, the subject device was ensured sterility by sterilization validation. Therefore, the differences on sterilization do not raise new questions about safety and effectiveness.

Comment 3

Through comparative analysis, the model was more than as the predicated products, while the puncture depths are same. Different models are only different in the outer diameter of the needle, which allowed to choose to meet blood volume needs. Different needle specification will be selected by physician per patient's condition and this different were addressed by performance tests. This difference does not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

## VII Summary of non-clinical testing

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

**Performance Testing for Disposable Blood Lancets**

| No | Testing item | Specification | Result |
|---|---|---|---|
| 01 | Appearance | Lancet should have the same color, no bubble, no flash, no slip. | Pass |
| 02 | Launch Length | The length of the needles in the Disposable Blood Lancets is different in different gauge. The general depth is 3.2mm | Pass |
| 03 | Sharpness | Penetration force ≤1.00N. | Pass |
| 04 | Exterior | The connection between needle and needle body should be firm. | Pass |

| | | | |
|---|---|---|---|
| 05 | | Cap twist should be smooth. | Pass |
| 06 | Initial bioburden | Initial bioburden of the device shall be less than 100CFU/g | Pass |
| 07 | Sterile | The sterile blood lancet shall be sterile | Pass |

**Biocompatibility testing**

Biocompatibility of the Disposable Blood Lancets were evaluated in accordance with ISO 10993-1:2018 for the body contact category. The following tests were performed, as recommended:

| | |
|---|---|
| Cytotoxic test | ISO 10993-5:2009 |
| Skin sensitization test | ISO 10993-10:2010 |
| Intracutaneous test | ISO 10993-10:2010 |
| Acute systemic toxicity test | ISO10993-11:2017 |
| Hemolysis test | ISO 10993-4:2017 |
| Pyrogen Test | USP <151> |

**Sterilization and shelf life testing**

- Irradiation sterilization validation per ISO 11173-1 and ISO 11173-3.
- Pyrogen testing per USP <151>
- Simulated shipping per ASTM D4169
- The 5 years shelf life of the device is determined based on stability study which includes ageing test.

**VIII Conclusion**

The Disposable Blood Lancets are substantially equivalent to its predicate device (Promisemed Blood Lancet). The differences between the predicate and subject device do not raise any new or different questions of safety or effectiveness. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.