November 29, 2022

Beijing Ruicheng Medical Supplies Co., Ltd.
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
China

Re: K222408
Trade/Device Name: Disposable Safety Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: August 8, 2022
Received: August 10, 2022

Dear Ray Wang:

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
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)*
K222408

Device Name
Disposable Safety Lancet

Indications for Use *(Describe)*
The Disposable 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

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K222408

1. Date of Preparation: 08/10/2022

2. Sponsor

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3. Submission Correspondent

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4. Proposed Device Identification

Trade Name: Disposable Safety Lancet.
Common Name: Disposable Safety Lancet.
Regulatory Information:
Classification: II
Product Code: FMK
Regulation Number: 21 CFR 878.4850
Review Panel: General & Plastic Surgery

Indication for Use Statement:
The Disposable Safety Lancet is intended for capillary blood sampling.

5. Predicate Device Identification

510(k) Number: K221368
Product Name: VeriFine Safety Lancet, VeriFine Mini-Safety Lancet
Manufacturer: Promisemed Hangzhou Meditech Co., Ltd

6. Device Description

The Disposable Safety Lancet is intended for capillary blood sampling.

The Disposable Safety Lancet include eleven models as IV, V, W2, M3, M3 PLUS, M4, M5, M5 MINI, M6, M7, E1.

The model “IV” of Disposable Safety Lancet include different needle core sizes: 21G,23G, 25G, 26G, 27G, 28G, 30G.
The model “V” of Disposable Safety Lancet include different needle core sizes: 21G, 23G, 25G, 26G, 27G, 28G, 30G.
The model “W2” of Disposable Safety Lancet include different needle core sizes: 21G, 23G, 25G, 26G, 27G, 28G, 30G.
The model “M3” of Disposable Safety Lancet include different needle core sizes: 21G, 23G, 25G, 26G, 27G, 28G, 30G.
The model “M3 PLUS” of Disposable Safety Lancet include different needle core sizes: 21G, 23G, 25G, 26G, 27G, 28G, 30G.
The model “M4” of Disposable Safety Lancet include different needle core sizes: 21G, 23G, 25G, 26G, 27G, 28G, 30G.
The model “M5” of Disposable Safety Lancet include different needle core sizes: 21G, 23G, 25G, 26G, 27G, 28G, 30G.
The model “M5 MINI” of Disposable Safety Lancet include different needle core sizes: 21G, 23G, 25G, 26G, 27G, 28G, 30G.
The model “M6” of Disposable Safety Lancet include different needle core sizes: 21G, 23G, 25G, 26G, 27G, 28G, 30G.
The model “M7” of Disposable Safety Lancet include different needle core sizes: 21G, 23G, 25G, 26G, 27G, 28G, 30G.
The model “E1” of Disposable Safety Lancet include different needle core sizes: 21G, 23G, 25G, 26G, 27G, 28G, 30G.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed

device complies with the following standards:

ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 10993-4:2017, Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood
USP34<151>, Rabbit Pyrogen Test

8. Substantially Equivalent Comparison Conclusion

ITEM	Proposed Device	Predicate Device K221368	Remark
Product name	Disposable Safety Lancet	VeriFine Safety Lancet, VeriFine Mini-Safety Lancet	SIMILAR
Product code	FMK	FMK	SAME
Regulation number	878.4850	878.4850	SAME
Class	II	II	SAME
Prescription/over-the-counter use	Over-The-Counter Use	Over-The-Counter Use	SAME
Intended Use	The Disposable Safety Lancet is intended for capillary blood sampling.	It is intended for capillary blood sampling.	SAME
Direction for use	1.Twist off the lancet protective cap clockwise or counterclockwise. 2.Grip the two side face of the lancet with thumb and middle finger respectively. 3. Use lancet against the skin of the blood sampling site, then press down the gland with the index finger quickly to eject. 4.Put the used lancet into dedicated recycling utensil.	1. Rotate the twisting cap less than half a round 2. Pull out the twisting cap 3. Place the device on the puncture site and push to start 4. Discard lancet into a sharp container 5. Press lightly on the finger toward the puncture site to obtain adequate blood sample	SIMILAR
Gauge	21G,23G,25G,26G,28G,30G	18G,21G,23G,25G,26G,28G,30G	SIMILAR
Needle Length (mm)	1.2, 1.5, 1.8, 2.1,2.4	1.2, 1.4, 1.6, 1.8, 2.0,2.2, 2.4, 2.6, 2.8	SIMILAR
Structure/Design	Disposable Safety Lancet are spring-loaded lancet. Disposable Safety Lancet are activated when you press the device against your finger.	VeriFine Safety Lancet and VeriFine Mini-Safety Lancet are spring-loaded lancet. VeriFine Safety lancet/VeriFine Mini-Safety Lancet are	SIMILAR

	Once activated the needle retracts into the body of the device which reduces the risk of injury as the result if an exposed needle.	activated when you press the device against your finger. Once activated the needle retracts into the body of the device which reduces the risk of injury as the result if an exposed needle. The first spring releases the needle into the skin and the second withdraws the needle back into the shield.	
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 core: SUS304 Excitation set:PS Shell:PP	Needle: Stainless steel Spring: Galvanized steel wire Shield, hub and Safety: ABS Trigger POM Lancet body cap: PE	ANALYSIS 1
Biocompatibility	Biocompatibility established	Biocompatibility established	SAME
Label/Labelin	Complied with 21 CFR part 801	Complied with 21 CFR part 801	SAME

Analysis 1: The raw materials of proposed devices may be different from the predicate devices. However, all the materials are known biocompatible materials that have been used in lancets or other similar medical devices.

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Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, VeriFine Safety Lancet cleared under K221368.