February 10, 2023

Suzhou Zhenwu Medical Co., Ltd.
% Evan Hu
Marketing & Technical Manager
Shanghai Mind-link Consulting Co., Ltd.
1399 Jiangyue Road, Minhang
Shanghai, 201114
China

Re: K223208
Trade/Device Name: Safety Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: January 19, 2023
Received: January 19, 2023

Dear Evan Hu:

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, PhD
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)*

K223208

Device Name

Safety Lancet

Indications for Use *(Describe)*

The 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.

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K223208
510(K) SUMMARY

1. **Preparation date: 1/27/2023**

2. **Submitter**

Manufacturer: Suzhou Zhenwu Medical Co., Ltd.
Address: No.248, Chijiawan Road, Beishe Town, Fenhu Development Area, Wujiang District, Suzhou City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA
Contact person: Kai Xu, General Manager, Tel: +86051263230688, zhenwu999xk@163.com
Submission correspondent: Evan Hu, 86-18616124827, Evan.hu@mind-link.net

3. **Device**

Trading name: Safety Lancet
Common name: Safety Lancet
Classification Name: Single Use Only Blood Lancet With an Integral Sharps Injury Prevention Feature
Classification: Class II
Product code: FMK

4. **Predicate device**

Predicate device: Tianjin Huahong Safety Lancet– K220370

5. **Device description**

The safety lancet consists of needle, needle core, protective cap, plug, trigger, spring, outer case and end cap. The sterile part of the safety 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.

The safety lancet is intended for capillary blood sampling. The device was designed to minimize the risk from accidental needle sticks with a used needle by application of a sharp injury prevention feature. The needle tip back into the safety lancet body automatically after launch and cannot be reused. The safety lancet can be disposed safely.

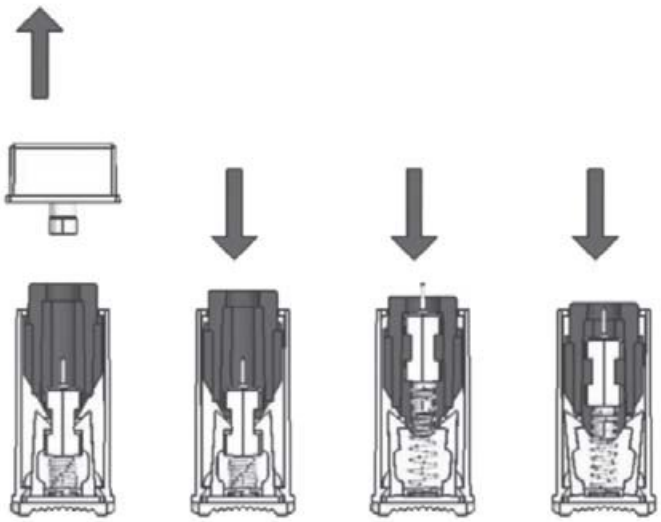

Figure 1. Schematic diagram of the working principle

Table 1. Device models

No.	Gauge	Needle Diameter(mm)		Exposed Needle Length(mm)		Color
		OD_{MIN}	OD_{MAX}	Length	Tolerance	
1	30G	0.298	0.320	1.2	±0.3	peacock blue
2	30G	0.298	0.320	1.6	±0.3	peacock blue
3	30G	0.298	0.320	1.8	±0.3	peacock blue
4	28G	0.349	0.370	1.8	±0.3	purple
5	26G	0.440	0.470	1.8	±0.3	yellow
6	23G	0.600	0.673	1.8	±0.3	Orange
7	23G	0.600	0.673	2.2	±0.3	Orange
8	23G	0.600	0.673	2.4	±0.3	Orange
9	21G	0.800	0.830	1.8	±0.3	Blue
10	21G	0.800	0.830	2.0	±0.3	Blue
11	21G	0.800	0.830	2.2	±0.3	Blue
12	21G	0.800	0.830	2.4	±0.3	Blue
13	21G Blade	0.800	0.830	2.0	±0.3	Bottle green
14	21G Blade	0.800	0.830	2.2	±0.3	Bottle green
15	21G Blade	0.800	0.830	2.4	±0.3	Bottle green
16	18G	1.200	1.300	2.0	±0.3	Rose
17	18G	1.200	1.300	2.2	±0.3	Rose
18	18G	1.200	1.300	2.4	±0.3	Rose
19	18G Blade	1.200	1.300	2.0	±0.3	Light green
20	18G Blade	1.200	1.300	2.2	±0.3	Light green
21	18G Blade	1.200	1.300	2.4	±0.3	Light green

6. Indications for use/Intended use

The safety lancet is intended for capillary blood sampling.

7. Comparison of technological characters between proposed and predicate devices

Table 2. Characters comparison

Characters	Proposed device (K223208-Safety Lancet)	Predicate device (K220370-Safety Lancet)	Remark
Product code	FMK	FMK	Same
Regulation No.	21 CFR 878.4850	21 CFR 878.4850	Same
Classification	Class II	Class II	Same
Indications for use	The safety lancet is intended for capillary blood sampling.	The safety lancet is intended for capillary blood sampling.	Same
Intended population	Adults and pediatrics. If user is under the age of 18, the safety lancet must be used by an adult or under the supervision of an adult.	Adults and pediatrics.	Same
Type of use	over-the-counter	over-the-counter	Same
Configuration and materials	Needle core: PE Needle: SUS304 Outer case, End case, Tigger: ABS Plug: TPE Spring: SWC	Needle core: PE, PP, Calcium powder Needle: stainless steel, silicone oil Housing, Button, Bottom, Protective cap, Small lid, Depth adjuster ring: ABS,PS	Similar #1
Needle Gauge	Normal: 30G, 28G, 26G, 23G, 21G, 18G Blade: 21G, 18G	Normal: 30G, 28G, 26G, 23G, 21G	Similar #2
Sterilization and SAL	Sterilized by gamma radiation SAL = 10^{-6}	Sterilized by gamma radiation SAL = 10^{-6}	Same
Single-use	Single use on one patient, no more than one use	Single use on one patient, no more than one use	Same
Sharp injury protection function	The puncture function can be only used after the cap was pulled off.	The puncture function can be only used after the cap was twisted off.	Similar #3

	Lancet retracts into body of device after activation.	Lancet retracts into body of device after activation.	
Safety feature	The force to activate the safety feature： round 8.8N Test access to the sharp: the needle shall not touch the sphere.	The force to activate the safety feature： 4-15N Test access to the sharp: the needle shall not touch the sphere.	Same
Exposed needle length/penetration depth (max)	1.2~2.4 mm 30G: 1.2, 1.6, 1.8 mm 28G: 1.8 mm 26G: 1.8 mm 23G: 1.8, 2.2, 2.4 mm 21G: 1.8, 2.0, 2.2, 2.4 mm 21G(Blade): 2.0, 2.2, 2.4 mm 18G: 2.0, 2.2, 2.4 mm 18G(Blade): 2.0, 2.2, 2.4 mm	1.0~3.0 mm 30G: 1.0, 1.6 mm 28G: 1.8 mm 26G: 1.8 mm 23G: 1.8 mm 21G: 2.2, 2.8, 3.0mm	Similar #4
Cap removal	Pull off Force: 3~9N	Twist off Force: Not revealed	Different #5
Shelf-life	5 years	5 years	Same
Biocompatibility	No cytotoxicity No irritation No skin sensitization No acute systemic toxicity No pyrogens	No cytotoxicity No irritation No skin sensitization No acute systemic toxicity No thermogenic reaction	Same

Similar #1

The safety lancet typically comprises three components, housing, needle, and spring. The component of the housing is mainly plastic. The component of the needle is stainless steel, and the spring consists of steel. Although the proposed and predicate devices use different materials, the types of components are unchanged. Besides, the performance testing reports, and biocompatibility testing reports show all the testing items meet requirements. This difference on materials has a minimal impact on the performance of the products.

In conclusion, the proposed device and predicate device are substantially equivalent.

Similar #2

The proposed device has six types of gauges, more than the predicate device, like 30G normal needle and 21G blade needle. Meanwhile, the proposed device has a new type-blade beveled needle tip. The differences between the blade and regular beveled tip are the beveled angle

and beveled face number; the blade beveled tip has a smaller bevel angle than the regular one, but more beveled faces. The needle length of the proposed device is included in the length range of the predicate device. The performance testing (e.g., needle removal force, puncture force testing) results demonstrated that the proposed device can be used safely and effectively.

In conclusion, the proposed device and predicate device are substantially equivalent.

Similar #3

The different methods to remove the protective cap will not affect sharps injury protection. The related report has verified the sharps injury protection function of the device. The needle tip is molded in plastic housing to ensure sterility. The different ways of activating the safety lancet do not influence the performance.

In conclusion, the proposed device and predicate device are substantially equivalent.

Similar #4

The exposed needle length/depth falls within the range of the Predicate device. The performance testing report verifies the proposed device's sharps injury protection function.

In conclusion, the proposed device and predicate device are substantially equivalent.

Different #5

The cap removal type is different. Unlike the predicate device twisting off the cap, the proposed device pulls off the cap. The cap removal force testing demonstrates the proposed device meets the internal requirements 3~9N; these requirements are similar to other cleared lancets.

In conclusion, the proposed device and predicate device are substantially equivalent.

8. Non-clinical testing results

(1) Physical performance testing

The proposed device's physical performance was tested to evaluate the overall non-clinical performance. Results demonstrated the device's safety and effectiveness by the following main items.

- Cap removal force testing.

Cap removal force testing was conducted in compliance with the manufacturer's internal requirements 3~9 N to ensure that end users could easily remove the cap without getting hurt.

- Needle removal force/Firmness
  Needle removal force testing was conducted in compliance with the requirements of ISO 7864:2016 to ensure the needle's firmness by bonding with the hub.
- Drop testing.
  Drop testing was conducted in compliance with the requirements of IEC 60068-2-32:1993, that the needle tip would not be exposed when it was dropped from a table with a fixed height.
- Puncture force testing.
  Puncture force testing was conducted in compliance with the requirements of ISO 7864:2016. The force was as low as possible to ensure the needle easily punctured the patients' skin.
- Safety Feature testing.
  The safety features were verified in compliance with the requirements of ISO 23908:2011 and Guidance for Industry and FDA Staff Medical Devices with Sharps Injury Prevention Features Document Issued on: August 9,2005, to ensure end users' safe use.

Other physical performance testing was conducted in compliance with the following standards.

(a) ISO 9626:2016 Stainless Steel Needle Tubing for the Manufacture of Medical Device.
(b) ISO 7864:2016 Sterile hypodermic needles for single use - requirements and test methods

(2) Sterility and Shelf-life

(a) ISO 11737-1:2018, Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
(b) ISO 11737-2:2019, Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
(c) ISO 11137-1:2006, Radiation sterilization of medical devices part 1: Requirements for the development, validation and routine control of the sterilization process of medical devices.
(d) ISO 11137-2:2013, Radiation sterilization of medical devices part 2: Determination of sterilization dose.
(e) ISO11137-3: 2017, Radiation sterilization of medical devices part 3: Dosage guidelines.
(f) ISO 11607-1:2019, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
(g) ASTM F1980: Standard for Accelerated Aging of Sterile Barrier Systems and Medical Devices
(h) ASTM D4169-16, Standard Practice For Performance Testing Of Shipping Containers And

Systems

(i) USP <71> Sterility Test

(3) Biocompatibility testing

(a) ISO10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

(b) ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.

(c) ISO 10993-10:2010, Biological evaluation on medical device Part 10: Test for irritation and Skin Sensitization.

(d) ISO 10993-11:2017, Biological evaluation of medical devices Part 11: Tests for systemic toxicity.

(e) USP <85> Bacterial Endotoxins Test

(f) USP <788>Particulate matter in injection

(g) USP <161>Medical Devices-Bacterial endotoxin and pyrogen tests

(4) Simulated clinical use testing

A simulated clinical use study was conducted on 500 device samples in compliance with the Guidance for Industry and FDA Staff Medical Devices with Sharps Injury Prevention Features Document Issued on: August 9, 2005. Results demonstrated the device's effectiveness and safety in a simulated clinical condition.

9. Clinical testing

No clinical testing is available for this device.

10. Conclusion

The differences between the predicate and the proposed device do not raise any new or different questions of safety or effectiveness. The proposed device is substantially equivalent to the predicate device with respect to indications for use and technological characteristics.