10/3/2022

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

Re: K221778
Trade/Device Name: Disposable Safety Lancets
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: June 10, 2022
Received: June 21, 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 Safety Lancets

Indications for Use *(Describe)*
Disposable Safety Lancets
The Disposable Safety Lancets 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 device contains a sharp injury protection feature.

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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Food and Drug Administration
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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."

K221778 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
Fax: +86-512 65495768
Email: shi.ye@medi-kyuan.com

Date: 08/30/2022

II Device

510K Number: K221778
Trade Name of Device: Disposable Safety Lancets
Common Name: Blood Lancets
Regulation Number: 21 CFR 878.4850
Regulation Name:
Single Use Only Blood Lancet with an Integral Sharps Injury Prevention Feature
Regulatory Class: II
Product code: FMK
Review Panel: General & Plastic Surgery

III Predicate Devices

Trade name:	SurgiLance® Safety Lancets
Common name:	Blood Lancets
Classification:	I-Lancet with Sharps Prevention Feature, 21CFR 878.4800
Product Code:	FMK
Premarket Notification:	K101145
Manufacturer:	MediPurpose Pte, Ltd.

IV Device description

The Disposable Safety Lancets consists 7 parts, include a lancet cap, body, slide, lancet, tip cover, spring and bottom. The models of the Disposable Safety Lancets are 18G; 21G; 23G; 26G; 28G; 30G; 32G; 33G. The Disposable Safety Lancets 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 device contains a sharp injury protection feature. The lancet is hit by pressure, and once the device strikes, the lancet needle

can puncture the skin. Used Gamma sterilization, and are products for single use.

V Indications for use

Disposable Safety Lancets

The Disposable Safety Lancets 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 device contains a sharp injury protection feature.

VI Comparison of technological characteristics with the predicate devices

The Disposable Safety 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 Safety Lancets and predicate devices do not alter suitability of the proposed device for its intended use.

Device feature	Subject Device	Predicate Device K101145	Comment
Indications for use	The Disposable Safety Lancets 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 device contains a sharp injury protection feature.	The SurgiLance® Safety Lancet is a puncture device to obtain micro blood samples. The SurgiLance® Safety Lancet has a sharps prevention feature to protect the user from a needlestick injury.	Similar Comment 1
Product code	FMK	FMK	Equivalent
Safety protection features	Yes	Yes	Equivalent
Reuse durability	Single use	Single use	Equivalent
Sterilization	Irradiation	Not available	Different Comment 2
Model	18G; 21G; 23G; 26G; 28G; 30G; 32G; 33G	SLN 170: 28G;	Different

<table>
<tr><th>Device feature</th><th>Subject Device</th><th>Predicate Device K101145</th><th>Comment</th></tr>
<tr><td></td><td></td><td>SLN 100: 21G;
SLN 200: 21G;
SLN 240: 21G;
SLN 300: 21G;
SLB 200: 18G;
SLB 250: 18G;
(Information gathered from MediPurpose Pte, Ltd. official website)</td><td>Comment 3</td></tr>
<tr><td>Penetration Depth</td><td><table><tr><td>18G</td><td>1.8mm</td></tr><tr><td>21G</td><td>1.8mm and 2.2mm</td></tr><tr><td>23G</td><td>1.8mm and 2.2mm</td></tr><tr><td>26G</td><td>1.8mm</td></tr><tr><td>28G</td><td>1.8mm</td></tr><tr><td>30G</td><td>1.8mm and 1.5mm</td></tr><tr><td>32G</td><td>1.5 mm</td></tr><tr><td>33G</td><td>1.5 mm</td></tr></table></td><td><table><tr><td>SLN 170- 28G</td><td>1.7mm</td></tr><tr><td>SLN 100- 21G</td><td>1.0mm</td></tr><tr><td>SLN 200- 21G</td><td>1.8mm</td></tr><tr><td>SLN 240- 21G</td><td>2.2mm</td></tr><tr><td>SLN 300- 21G</td><td>2.8mm</td></tr><tr><td>SLB 200- 18G</td><td>1.8mm</td></tr><tr><td>SLB 250- 18G</td><td>2.3mm</td></tr></table>(Information gathered from MediPurpose Pte, Ltd. official website)</td><td></td></tr>
<tr><td>Needle Length</td><td><table><tr><td>18G</td><td>18.3mm±1.0mm</td></tr><tr><td>21G</td><td>18.3mm±1.0mm
18.7mm±1.0mm</td></tr><tr><td>23G</td><td>18.3mm±1.0mm
18.7mm±1.0mm</td></tr><tr><td>26G</td><td>18.3mm±1.0mm</td></tr><tr><td>28G</td><td>18.3mm±1.0mm</td></tr></table></td><td><table><tr><td>SLN 170- 28G</td><td>17.7mm</td></tr><tr><td>SLN 100- 21G</td><td>17.3mm</td></tr><tr><td>SLN 200- 21G</td><td>17.7mm</td></tr><tr><td>SLN 240- 21G</td><td>18.1mm</td></tr><tr><td>SLN 300- 21G</td><td>18.6mm</td></tr><tr><td>SLB 200- 18G</td><td>17.7mm</td></tr><tr><td>SLB 250- 18G</td><td>18.2mm</td></tr></table></td><td></td></tr>
</table>

Device feature	Subject Device		Predicate Device K101145	Comment
	30G	18.3mm±1.0mm 18.1mm±1.0mm		
	32G	18.1mm±1.0mm		
	33G	18.1mm±1.0mm		
Materials of parts in contact with human body	Lancet needle: 304 stainless steel; Body and cap: ABS or PP;		Lancet needle: medical grade stainless steel; Housing and cap: plastics	Similar Comment 4

Discussion:

Comment 1

Minor rewording of the Intended Use statement has been made for the purpose of streamlining the information provided to the user. The subject device and the predicate device have the same intended use, to puncture the skin to obtain drops of blood for diagnostic purposes. The same basic technology characteristics for a lancet with sharps injury prevention of Disposable Safety Lancets as compared with the predicate device. The general purpose of the device and its function remain unchanged. The minor rewording of the Intended Use statement does not raise different questions of safety and effectiveness.

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

The needle length is similar as the predicate device, while it is the penetration depth and diameter of needle rather than needle length that affect the amount of blood collected. However, the different of models and penetration depth are just in dimension. Different needle diameters and depths of lancet was allowed to choose to meet blood volume needs and the difference were addressed by performance tests. Different needle specification will be selected by physician per patient's condition. 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.

Comment 4

The subject device utilizes some of the same materials, specifically the use of medical grade stainless steel for the lancet needles but may use different types plastics for the bodies, caps. All the materials are known biocompatible materials that have been used in lancets or other similar medical devices, and the materials of subject device were demonstrated by the biocompatibility tests done. The differences between the subject device and predicate device do 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.

No	Testing item	Specification	Result
01	Appearance	Disposable Safety Lancets the surface should be smooth without edge, no dirt and damage, deformation and other poor appearance.	Pass
02	Launch Length	The length of the needles in the Disposable Safety Lancet is different in different genders and ages. The launch length of the needle is determined according to the length of the purchase, and the general emission length is 1.2mm-2.8mm.	Pass
03	Sharpness	Penetration force ≤1.00N.	Pass
04	Feature	The tip of the needle can shrink quickly after firing, and the tip of the needle is not exposed.	Pass
05		Disposable Safety Lancets Only one launch, not another.	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 Safety Lancets were evaluated in accordance with ISO 10993-1:2018 for the body contact category. The following tests were performed, as recommended:

Item	Test method	Test results
Cytotoxic test	ISO 10993-5:2009	No Cytotoxicity
Skin sensitization test	ISO 10993-10:2010	No Skin sensitization
Intracutaneous test	ISO 10993-10:2010	No irritation
Acute systemic toxicity test	ISO10993-11:2017	No Acute Systemic Toxicity
Hemolysis test	ISO 10993-4:2017	No Hemolysis
Pyrogen Test	USP <151>	Non- pyrogen

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 Safety Lancets are substantially equivalent to its predicate device (SurgiLance® Safety Lancets). 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.