June 13, 2023

Bosungmeditech Co., Ltd.
℅ Andrew Chun
President
Andrew Chun
6300 Old York Rd. Apt. 914,
Philip Murray House
Philadelphia, Pennsylvania 19141

Re: K230759
Trade/Device Name: SafeLan® (2 models/SafeLan 26G, SafeLan 30G), SafeLan®-Pro (1 model/SafeLan®-Pro)
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRK
Dated: March 2, 2023
Received: March 20, 2023

Dear Andrew Chun:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.06.13 09:41:56 -04'00'

Mark Trumbore, 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)*
K230759

Device Name
SafeLan®, SafeLan®-Pro

Indications for Use *(Describe)*
SafeLan® is sterile, single use device that has been designed for single patient use by lay users in a home. Their intended use is for performing skin punctures on patients for the purpose of obtaining capillary blood samples.

SafeLan®-Pro: Use with SafeLan® for capillary blood sampling and the SafeLan®-Pro as the multiple use execution device which the SafeLan® lancet attaches.

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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510(k) Summary

Prepared on: 2023-06-06

Contact Details

21 CFR 807.92(a)(1)

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Correspondent Contact Telephone	215-2687249
Correspondent Contact	Mr. Andrew Chun
Correspondent Contact Email	jcs268268@gmail.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SafeLan® (2 models/SafeLan 26G, SafeLan 30G); SafeLan®-Pro (1 model/SafeLan®-Pro)
Common Name	Blood lancets
Classification Name	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature
Regulation Number	878.4850
Product Code	QRK

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K214022	Accu-Check Softclix Blood Lancing System	QRK

Device Description Summary

21 CFR 807.92(a)(4)

1. SafeLan®
SafeLan® blood lancet is a small medical device used for capillary blood sampling. The SafeLan® is a blood lancet consisting of protective cap, needle protector, spring, lancet, and needle. The main component of blood lancet is the needle. The needle is the small, sharp objects that are used to prick the skin to obtain a small quantity of blood for testing. SafeLan® has 2 models depending on the diameter of the needle.

- SafeLan® 26G: 0.46±0.05mm
- SafeLan® 30G: 0.30±0.05mm

Lancing device (SafeLan®-Pro) combines with the SafeLan® to operate the needle to prick the skin.

2. SafeLan®-Pro
SafeLan®-Pro is used with SafeLan® to draw capillary blood from the fingertip, for testing utilizing small amounts of blood. SafeLan® is used with compatible lancing device (SafeLan®-Pro) for capillary blood sampling.

SafeLan®-Pro consists of loading handle, operation button, depth adjustment part, and depth adjustment confirmation part.

The operating principle of SafeLan®-Pro is driven by force of the spring. The simple operating sequence is as follows.

1) Insert the SafeLan® clockwise to the front thread of the SafeLan®-Pro.
2) Pull the needle protector of SafeLan® to remove it.
3) Pull and release the loading handle of SafeLan®-Pro.
4) Press the operation button of SafeLan®-Pro.
5) Remove the used SafeLan® from the SafeLan®-Pro by turning them counterclockwise.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

SafeLan® is sterile, single use device that has been designed for single patient use by lay users in a home or general environment. Their intended use is for performing skin punctures on patients for the purpose of obtaining capillary blood samples.

SafeLan®-Pro: Use with SafeLan® for capillary blood sampling.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The described indications for use (e.g. General and Plastic Surgery) for the proposed device is exactly the same as the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

Technological Comparison

Many aspects of the proposed device are similar to those of the predicate device, except for some minor differences:

Note 1: Anatomical sites, Intended population, Depth of penetration
Anatomical sites, intended population, and needle gauge of proposed device are different with predicate device. (*1) Krelza at al. recommended that if the recommended puncture site is finger, the recommended incision depth is up to 2.4mm for child older than 8 years and adults.
Anatomical site of proposed device is fingertip, intended population of proposed device is child older than 8 years and adults, and maximum depth of proposed device is 1.75mm.
Therefore, the maximum depth of the proposed device's needle depending on the anatomical sites and intended population is valid and this difference in the proposed device and predicate device do not raise concerns related to device safety and effectiveness.

* 1: Capillary blood sampling: national recommendations on behalf of the Croatian Society of Medical Biochemistry and Laboratory Medicine, http://dx.doi.org/10.11613/BM.2015.034

Note 2: Needle Gauge (Out Diameter)
The gauge of proposed device is different from the lancets of predicate device. In order to confirm the performance between the different lancet specifications, proposed device was verified by measuring the needle gauge and the needle of proposed device was firmly fixed in lancet housing at each time point of accelerated aging test. The safety and effectiveness of proposed device was substantially equivalent to predicate device.

Note 3: Depth Adjustment
The proposed device has 5 levels of puncture depth, which are adjustable by rotating the selector cap. The predicate device has 11 levels of puncture depth, which are adjustable by rotating the rotatable cap and AST cap.
The mechanical performance test was performed to verify the percussion of lancets for each puncture depth. The firmness force test was also performed in the accelerated aging test of proposed device.
According to the test result, puncture depths and exposed needle length of proposed device and met its specifications, and the firmness force was within acceptance criteria in the accelerated aging test. This difference does not affect the basic design principle, usage, effectiveness and safety of the proposed device, and no question is raised regarding to effectiveness and safety.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Not Applicable