January 13, 2025

HLB Co., Ltd. Healthcare
℅ Kyung-Hwan Kim
Representative Consultant, RA/QA
SMB Korea Co.
7, Boramae-ro 5ga-gil, Dongjak-gu
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Seoul, 07071
Korea, South

Re: K243533
Trade/Device Name: Sterilized Eol Auto Lancet; Sterilized Eol Lancet Plus
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK, QRK
Dated: November 15, 2024
Received: November 15, 2024

Dear Kyung-Hwan Kim:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2025.01.13 07:31:09 -05'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243533

Device Name

Sterilized Eol Auto Lancet;
Sterilized Eol Lancet Plus

Indications for Use *(Describe)*

It 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

[Complying with 21 CFR 807.92]

I. SUBMITTER INFORMATION

Company Name:	HLB Co., LTD. Healthcare
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510(k) Owner:	SMB Korea Co.
510(k) Preparer:	Mr. Kyung-hwan, Kim, Representative Consultant RA/QA

II. DATE PREPARED

November 15, 2024

III. DEVICE IDENTIFICATION

Trade or Proprietary Name:	Sterilized Eol Auto Lancet, Sterilized Eol Lancet Plus
Common or Usual Name:	Blood Lancet
Classification Name:	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature, Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature
Regulatory Class:	II
Product Code:	FMK, QRK
Regulation Number:	21 CFR 878.4850

IV. PREDICATE DEVICE

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

V. DEVICE DESCRIPTION

The Sterilized Eol Auto Lancet and Sterilized Eol Lancet Plus are single-use, surgical steel devices housed in plastic, designed to puncture a fingertip for capillary blood sampling. They can be used anytime and anywhere to measure blood glucose levels in diabetic patients. The needle sleeve serves as a sterile barrier, sterilized to an SAL of 10-6 through

irradiation. The product has a shelf life of 3 years.

The Sterilized Eol Auto Lancet includes a protective cap, handle, needle, button, lancing device, and two springs. To activate, simply remove the protective cap, place the button on the skin, and press the lancet. After use, the needle retracts into the device for safe handling.

The Sterilized Eol Lancet Plus includes a protective cap, handle, and needle. It can be used alone or with a lancing device that offers an adjustable tip and varying depth settings.

VI. INDICATION FOR USE STATEMENT

It is intended for capillary blood sampling.

VII. TECHNOLOGICAL CHARACTERISTICS COMPARISON

The comparison chart below supports the determination of substantial equivalence between the Sterilized Eol Auto Lancet, Sterilized Eol Lancet Plus, and the primary predicate (K221368) regarding intended use, technological characteristics, and principles of operation.

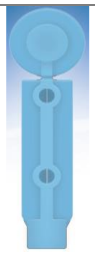
Device Comparison Chart: Similarities and Differences – Sterilized Eol Auto Lancet

	SUBJECT Device	**PRIMARY PREDICATE Device (K221368)**	**Significant Difference**
Manufacturer	HLB Co., LTD. Healthcare	Promisemed Hangzhou Meditech Co., Ltd.	–
Trade Name	Sterilized Eol Auto Lancet	VeriFine Safety Lancet VeriFine Mini-Safety Lancet	–
Regulation Description	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature	–
Regulation Number	21 CFR 878.4850	21 CFR 878.4850	No difference.
Product Code	FMK	FMK	No difference.
Class	II	II	No difference.
Patient Population	All ages	All ages	No difference.
Prescription or OTC	OTC	OTC	No difference.
Intended Use/ Indications for Use	It is intended for capillary blood sampling.	It is intended for capillary blood sampling.	No difference.
Direction for use	1. Remove the lancet's protective cap by unscrewing it. 2. Draw blood from a site that has been sterilized with	1. Rotate the twisting cap less than half a round. 2. Pull out the twisting cap. 3. Place the device on	Similarly: There is no significant difference between subject device and predicate device. They describe the same

	SUBJECT Device	PRIMARY PREDICATE Device (K221368)	Significant Difference
	alcohol swabs. 3. Press the lancet's push button to draw blood from the desired site.	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.	process without notable distinctions.
Number of Uses	Single use	Single use	No difference.
Design and Structure	 To activate, simply remove the protective cap, place the button on the skin, and press the lancet. After use, the needle retracts into the device for safe handling.	 VeriFine Safety Lancet and VeriFine Mini-Safety Lancet are spring-loaded lancet. VeriFine Safety lancet/ VeriFine Mini-Safety Lancet are 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.	Difference: The subject device has minor shape changes compared to predicate device, but these are within the acceptable range and do not introduce a significantly different design. Performance tests address these differences, ensuring no impact on design principles, usage, effectiveness, or safety.
Material	Needle: Stainless steel Spring: Galvanized steel housing, hub and Safety: HDPE Trigger: PP Lancet body, cap: PP	Needle: Stainless steel Spring: Galvanized steel wire Shield, hub and Safety: ABS Trigger: POM Lancet body, cap: PE	No difference.
Gauge	26G, 28G, 30G	18G, 21G, 23G, 25G, 26G,	Similarly:

	SUBJECT Device	PRIMARY PREDICATE Device (K221368)	Significant Difference
		28G, 30G	The subject device's gauge is within the predicate device's range.
Needle Length (mm)	1.5	1.2, 1.4, 1.6, 1.8, 2.0, 2.2, 2.4, 2.6, 2.8	Similarly: The subject device's gauge is within the predicate device's range.
Sterilization Method	Electron beam	Gamma	No difference.
Shelf-Life	3 years	5 years	No difference.
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	No difference.

Device Comparison Chart: Similarities and Differences – Sterilized Eol Lancet Plus

	SUBJECT Device	PRIMARY PREDICATE Device (K221368)	Significant Difference
Manufacturer	HLB Co., LTD. Healthcare	Promisemed Hangzhou Meditech Co., Ltd.	–
Trade Name	Sterilized Eol Lancet Plus	Promisemed® Blood Lancet	–
Regulation Description	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature	–
Regulation Number	21 CFR 878.4850	21 CFR 878.4850	No difference.
Product Code	QRK	QRK	No difference.
Class	II	II	No difference.
Patient Population	All ages	All ages	No difference.
Prescription/OTC	OTC	OTC	No difference.
Intended use/ Indications for Use	It is intended for capillary blood sampling.	It is intended for capillary blood sampling.	No difference.
Number of Uses	Base (lancing device): Not applicable Lancet: single use	Base (lancing device): Not applicable Lancet: single use	No difference
Design and Component	 Stainless steel needle encapsulated in a plastic body and cap, the cap is twisted off to expose the needle for use.	 Stainless steel needle encapsulated in a plastic body and cap, the cap is twisted off to expose the needle for use.	Difference: The subject device has minor shape changes compared to predicate device, but these are within the acceptable range and do not introduce a significantly different design. Performance tests address these differences, ensuring no

	SUBJECT Device	PRIMARY PREDICATE Device (K221368)	Significant Difference
			impact on design principles, usage, effectiveness, or safety.
Material	Needle: Stainless steel Handle, Protective cap: PE	Needle: Stainless steel Handle, Protective cap: PE	No difference.
Gauge	26G, 28G, 30G	28G, 30G, 32G, 33G	Similarly: The subject device's gauge is within the predicate device's range.
Needle Length (mm)	3.0	3.0	No difference.
Sterilization Method	Electron beam	Gamma	No difference.
Shelf-Life	3 years	5 years	No difference.
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	No difference.

VIII. NON-CLINICAL PERFORMANCE DATA

The following tests were conducted:

Sterilization and Shelf-Life

The sterility of the subject devices is ensured through a sterilization method validated according to ISO 11137-1:2006/AMD 2:2018, ISO 11137-2:2013/AMD 1:2022, and ISO 11137-3:2017.

The shelf life of the device is three years from the date of manufacture, as per ASTM F1980-21, Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices.

Biocompatibility Testing

Biocompatibility classification follows the FDA Guidance based on ISO 10993-1:2019, which outlines the biological evaluation and testing of medical devices within a risk management framework.

The devices in question are classified as Externally Communicating Medical Devices intended for circulating blood with limited exposure (≤24 hours).

These devices have successfully completed all testing required by ISO 10993-1:2019 and the associated FDA guidance document.

Performance testing

The Sterilized Eol Auto Lancet and Sterilized Eol Lancet Plus have successfully completed comprehensive bench testing, demonstrating full compliance with safety and effectiveness requirements. The testing protocol adhered to the FDA Guidance for

Industry and FDA Staff on Medical Devices with Sharps Injury Prevention Features (dated August 30, 2024) and the special controls outlined in 21 CFR 878.4850 for blood lancets. Performance evaluation results confirmed that both devices successfully met all specified regulatory requirements and safety standards.

IX. CLINICAL TESTS

Clinical performance testing was not deemed necessary as the non-clinical testing was sufficient to demonstrate substantial equivalence.

X. CONCLUSIONS

Based on the comparison of intended use, technological characteristics, and performance testing results, the Sterilized Eol Auto Lancet and Sterilized Eol Lancet Plus are substantially equivalent to the predicate device. The non-clinical test results demonstrate that the devices are as safe and effective as the predicate device. The differences in technological characteristics do not raise any new issues of safety or effectiveness. Therefore, these devices are suitable for their intended use in capillary blood sampling.