December 6, 2023

Sewon Medical Co.
℅ Kyung-Hwan Kim
Representative Consultant RA/QA
SMB Korea
#606, #607, 7, Boramae-ro 5ga-gil
Donjak-gu
Seoul, 07071
Korea, South

Re: K230712
Trade/Device Name: SG Lanset I, SG Lancets, Soft Lancets
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRK
Dated: October 30, 2023
Received: November 6, 2023

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.

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.12.06 10:52:58 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K230712

Device Name
SG LANSET I, SG LANCETS and SOFT LANCETS

Indications for Use *(Describe)*
The SG LANSET I, SG LANCETS and SOFT LANCETS are indicated to obtain a capillary blood sample from the side of a fingertip for testing utilizing small amounts of blood.

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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510(k) Summary

[Complying with 21 CFR 807.92]

I. SUBMISSION SPONSOR

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Contact: Kyung-hwan Kim, Representative Consultant, QA
Email: info@smbkorea.com

III. DATE PREPARED

October 30, 2023

IV. DEVICE IDENTIFICATION

Trade or Proprietary Name:	SG LANSET I, SG LANCETS and SOFT LANCETS
Common or Usual Name:	Blood Lancet
Classification Name:	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature (878.4850)
Regulatory Class:	II
Product Code:	QRK
Classification Panel:	General & Plastic Surgery

V. LEGALLY MARKETED PREDICATE DEVICE(S)

Primary Predicate Device:
K214022, Accu-Chek Softclix Blood Lancing System / Roche Diabetes Care, Inc.

Reference Device:
K220387, Disposable Blood Lancets / Suzhou Kyuan Medical Apparatus Co., Ltd.

VI. DEVICE DESCRIPTION

The SG LANSET I, SG LANCETS and SOFT LANCETS are a single use, sterilized by gamma

radiation, which is a pointed piece of surgical steel encased in plastic, used to puncture the skin on one's finger to get a blood sample. The SG LANSET I, SG LANCETS and SOFT LANCETS can be used anytime and anywhere to obtain a blood sample form diabetic patients to measure their blood sugar level. A cap is included to protect the needle from becoming contaminated with dust, etc. The cap completely seals the needle making it impossible for any foreign material to come in contact with the needle. This ensures safe storage and easy portability.

The lancing device used with most blood lancets, offers an adjustable tip with variety depth settings for quick, comfortable and easy blood sampling.

VII. Accessories for the Product, Integral Parts of Package

All compatible accessories (i.e., lancing device) that can be used with the Blood Lancet are listed in the table below but are **not included** with these devices:

No.	Model Name	Compatible Blood Lancet	Appearance	Description
1	Accu-Chek Softclix (K214022)	SOFT LANCETS		The lancing device uses compatible lancets to obtain a drop of blood from the fingertip. The penetration depth can be selected to match any type of skin. Lancing device may be adjusted penetration depth by turning the Comfort Dial. Each level marked with dots to enable you to precisely adjust to your individual skin type. The higher the number visible in the depth indicator window, the greater the depth setting. Also, the lancing device is intended for use by a single person and is not suitable for testing different persons with the same device as this may lead to infections.
2	Suzhou Lancing Device (K220387)	SG LANSET I, SG LANCETS		

VIII. INDICATION FOR USE STATEMENT

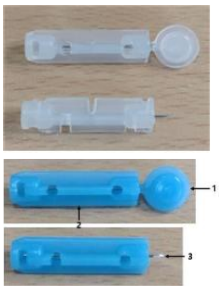
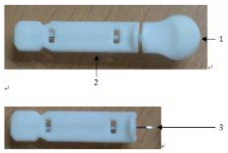
The SG LANSET I, SG LANCETS and SOFT LANCETS are indicated to obtain a capillary blood sample from the side of a fingertip for testing utilizing small amounts of blood.

IX. SUBSTANTIAL EQUIVALENT DISCUSSION

The comparison chart below provides evidence to facilitate the substantial equivalence

determination between SG LANSET I, SG LANCETS and SOFT LANCETS to the primary predicate (K214022) and reference device (K220387) with respect to intended use, technological characteristics and principles of operation.

	SUBJECT Device	Primary PREDICATE Device (K214022)	REFERENCE Device (K220387)	Significant Difference
Manufacturer	SEWON MEDICAL CO.	Roche Diabetes Care, Inc.	Suzhou Kyuan Medical Apparatus Co., Ltd.	–
Trade Name	SG LANCET I, SG LANCETS and SOFT LANCETS	Accu-Chek Softclix Blood Lancing System	Disposable Blood Lancets	–
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	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature	–
Regulation Number	21 CFR 878.4850	21 CFR 878.4850	21 CFR 878.4850	No difference.
Product Code	QRK	QRK, QRL	QRK, QRL	No difference.
Class	II	II	II	No difference.
Patient Population	All ages	All ages	All ages	No difference.
Prescription/OTC	OTC	OTC	OTC	No difference.
Intended use	The SG LANSET I, SG LANCETS and SOFT LANCETS are indicated to obtain a capillary blood sample from the side of a fingertip for testing utilizing small amounts of blood.	The Accu-Chek Softclix Blood Lancing System is indicated to obtain a capillary blood sample from the side of a fingertip for testing utilizing small amounts of blood.	The product 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 lancet is intended to be assembled with a lancing device, such that once the lancing device is launched, the needle of the lancet can prick the skin.	No difference.
Indications for Use	The sterile lancets for single use are to be used with the reusable lancing device that is to be cleaned and disinfected between each use, and then the lancets are to be disposed of. This device is for use only on a single patient in a home setting. This device is not suitable for use by healthcare	The sterile, single-use lancets are to be used with the reusable lancing device that is to be cleaned and disinfected between each use, and then the lancets are to be disposed of. This system is for use only on a single patient in a home setting. This system is not suitable for use by healthcare professionals with	The product 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 lancet is intended to be assembled with a lancing device, such that once the lancing device is launched, the needle of the lancet can prick the skin.	No difference.

	SUBJECT Device	Primary PREDICATE Device (K214022)	REFERENCE Device (K220387)	Significant Difference
	professionals with multiple patients in a healthcare setting.	multiple patients in a healthcare setting.		
Number of Uses	Base (lancing device): Not applicable Lancet: single use	Base (lancing device): multiple use Lancet: single use	Base (lancing device): multiple use Lancet: single use	Difference: The subject device lacks a lancing device.
Design and Component	Lancing Device (and AST Cap): Not applicable Lancet: [SG LANCET I, SG LANCETS]  [SOFT LANCETS] 	Lancing Device (and AST Cap):  Lancet: 	Lancing Device (and AST Cap):  Lancet: 	Difference: There are a minor shape changes in the subject device comparing to the predicate devices. However, the difference in shape is very minor, and the shape of the subject device is within the range of the predicate devices; it is not introducing s significantly different design, and this different were addressed by performance tests. This difference does not affect the basic design principle, usage, effectiveness and safety of the subject device.
Needle Material	Stainless Steel	Stainless Steel	Stainless Steel	No difference.
Needle	0.5mm(25G); 0.36mm(28G); 0.3mm(30G); and 3 facets cut	0.4mm(28G); beveled cut with 3 facets	18G, 21G, 23G, 26G, 0.36mm(28G), 0.3mm(30G), 32G, and 33G;	Similarly: There is slightly different needle length between the subject and predicate devices. However, the guage of the subject device is within the range of the predicate devices; it is not introducing s significantly different design, and this different were addressed by performance tests. This difference does not affect the basic design principle, usage, effectiveness and safety of the

	SUBJECT Device	Primary PREDICATE Device (K214022)	REFERENCE Device (K220387)	Significant Difference
				subject device.
Depth adjustment	n/a	11 levels by twisting cap	10 level adjustable tip for easy and adjustable skin penetration	Difference: The subject device lacks a lancing device.
Lancet needle dimensions (Needle + Handle)	- Length of Lancet 25.22mm ~ 25.87mm	- Length of Lancet 25.22mm ~ 25.31mm	- Length of Lancet 26.38mm ~ 26.48mm	Similarly: The length of the lancet is not significantly different between the subject device and predicate/reference device. 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.
Lancet needle penetration depth	- **SG LANCET I, SG LANCETS (Used with K214022 lancing device)** 1step: 0.29~0.31mm; 2step: 0.48~0.50mm; 3step: 0.76~0.78mm; 4step: 0.86~0.88mm; 5step: 0.87~0.89mm; and 6step: 0.94~0.96mm - **SOFT LANCETS (Used with K220387 lancing device)** 0.5step: 0.80mm±0.1; 1step: 0.95mm±0.1; 1.5step: 1.10mm±0.1; 2step: 1.25mm±0.1; 2.5step: 1.40mm±0.1; 3step: 1.55mm±0.1; 3.5step: 1.70mm±0.1; 4step: 1.85mm±0.1; 4.5step: 2.00mm±0.1; 5step: 2.15mm±0.1; and 5.5step: 2.30mm±0.1	- **Used with K214022 lancing device** 0.5step: 0.80mm±0.1; 1step: 0.95mm±0.1; 1.5step: 1.10mm±0.1; 2step: 1.25mm±0.1; 2.5step: 1.40mm±0.1; 3step: 1.55mm±0.1; 3.5step: 1.70mm±0.1; 4step: 1.85mm±0.1; 4.5step: 2.00mm±0.1; 5step: 2.15mm±0.1; and 5.5step: 2.30mm±0.1	- **Used with K220387 lancing device** 1step: 0.29~0.31mm; 2step: 0.48~0.50mm; 3step: 0.76~0.78mm; 4step: 0.86~0.88mm; 5step: 0.87~0.89mm; and 6step: 0.94~0.96mm	Through comparative analysis, while the puncture depths are same. Different needle specification will be selected by physician per patient's condition and this different were addressed by performance tests. 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.
Sterilization Method	Gamma (It is provided with a minimum	Gamma (It is provided with a minimum	Gamma (It is provided with a minimum	No difference.

	SUBJECT Device	Primary PREDICATE Device (K214022)	REFERENCE Device (K220387)	Significant Difference
	sterility assurance level of 10-6, validated in compliance to ISO 11137-1/2/3.)	sterility assurance level of 10-6, validated in compliance to ISO 11137-1/2/3.)	sterility assurance level of 10-6, validated in compliance to ISO 11137-1/2/3.)	
Shelf-Life	5 years	5 years	5 years	No difference.
Performance Testing	Dimension: Pass Inner-Outer surface: Pass Draw test: Pass	Dimension: Pass Inner-Outer surface: Pass Draw test: Pass	Dimension: Pass Inner-Outer surface: Pass Draw test: Pass	No difference.
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	No difference.
Prescription/OTC	OTC	OTC	OTC	No difference.
Sharps injury prevention	Lancets are covered by a sterile barrier cap until twisted off before use. Until firing, the lancet is contained within the lancing device housing. Immediately after firing, the lancet is automatically retracted back into housing. An ejector sleeve can then be pulled forward for contactless disposal of the lancet.	Lancets are covered by a sterile barrier cap until twisted off before use. Until firing, the lancet is contained within the lancing device housing. Immediately after firing, the lancet is automatically retracted back into housing. An ejector sleeve can then be pulled forward for contactless disposal of the lancet.	Lancets are covered by a sterile barrier cap until twisted off before use. Until firing, the lancet is contained within the lancing device housing. Immediately after firing, the lancet is automatically retracted back into housing. An ejector sleeve can then be pulled forward for contactless disposal of the lancet.	No difference.

X. NONCLINICAL PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Performance testing

Bench testing was performed to ensure the demonstration of safety and effectiveness of the subject device in accordance with the Guidance for Industry and FDA Staff – Medical Devices with Sharps Injury Prevention Features, issued on August 9, 2005 and special controls (878.4850 Blood lancets).

The results of the performance test demonstrated that SG LANSET I, SG LANCETS and SOFT LANCETS met the requirements.

Biocompatibility Testing

Biocompatibility classification is based on the FDA Guidance Use of International

Standard ISO 10993-1, “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process.”

The subject devices are classified as an Externally Communicating Medical Devices, Circulating blood, Limited exposure (≤24 hours).

The subject devices have fulfilled all testing required per ISO 10993-1 and FDA Guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

Sterilization and Shelf-Life

The sterility of the subject devices is assured using a sterilization method validated in accordance with ISO 11137-1:2006/AMD 2:2018, Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices — Amendment 2, ISO 11137-2:2013/AMD 1:2022, Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose — Amendment 1, and ISO 11137-3:2017, Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control.

The shelf life of the subject device is five (5) years from the date of manufacture in accordance with ASTM F1980-21, Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices.

XI. CLINICAL TESTS

This 510(k) does not include data from clinical tests.

XII. CONCLUSIONS

Based on the above information, the SG LANSET I, SG LANCETS and SOFT LANCETS are substantially equivalent to the predicate devices listed above. The information contained in this submission supports the fact that the SG LANSET I, SG LANCETS and SOFT LANCETS are as safe and effective as the predicate devices.