October 8, 2024

Sejoy Biomedical Co., Ltd
Yinting Lan
Regulatory Affairs Specialist
Area C, Building 2, No.365 Wuzhou Road
Yuhang Economic Development Zone
Hangzhou City, Zhejiang 311100
China

Re: K240640
Trade/Device Name: Sejoy Blood Glucose Monitoring System and
Sejoy Advance Link Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: September 6, 2024
Received: September 6, 2024

Dear Yinting Lan:

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 and Part 809); 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,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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)*
K240640

Device Name
Sejoy Advance Link Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Sejoy Advance Link Blood Glucose Monitoring System is composed of the Sejoy Advance Link Blood Glucose Meter and Sejoy Blood Glucose Test Strips. The Sejoy Advance Link Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips. The Sejoy Advance Link Blood Glucose Monitoring System is intended for self-testing outside the body (in-vitro diagnostic use), by individuals with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended to be used by a single person and should not be shared. The system should not be used for the diagnosis of, or screening for diabetes or for neonatal use.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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See PRA Statement below.

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Device Name
Sejoy Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Sejoy Blood Glucose Monitoring System is composed of the Sejoy Blood Glucose Meter and Sejoy Blood Glucose Test Strips. The Sejoy Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood collected from the fingertip. The Sejoy Blood Glucose Monitoring System is intended for self-testing outside the body (in-vitro diagnostic use), by individuals with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended to be used by a single person and should not be shared. The system should not be used for the diagnosis of, or screening for diabetes or for neonatal use.

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.

Traditional 510(k)

510(k) Summary

The assigned 510(k) number is K240640

Sponsor	SEJOY Biomedical Co., Ltd. Area C, Building 2, No.365 Wuzhou Road,Yuhang Economic Development Zone,Hangzhou City, 311100,Zhejiang, China
Correspondent	Yingting Lan, Regulatory Affairs Specialist Phone:+86-571-81957767 E-mail:lanyt@sejoy.com
Date Prepared	August 20th, 2024
Device Trade Name	Sejoy Blood Glucose Monitoring System Sejoy Advance Link Blood Glucose Monitoring System
Common Name	Glucose Test System
Classification	Class II device (21 CFR § 862.1345), Product Code NBW
Predicate Device	OneTouch Verio Reflect Glucose Monitoring System (K193475) Product Code NBW

Intended Use/Indications For Use

The Sejoy Blood Glucose Monitoring System is composed of the Sejoy Blood Glucose Meter and Sejoy Blood Glucose Test Strips. The Sejoy Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood collected from the fingertip. The Sejoy Blood Glucose Monitoring System is intended for self-testing outside the body (in-vitro diagnostic use), by individuals with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended to be used by a single

person and should not be shared. The system should not be used for the diagnosis of, or screening for diabetes or for neonatal use.

The Sejoy Advance Link Blood Glucose Monitoring System is composed of the Sejoy Advance Link Blood Glucose Meter and Sejoy Blood Glucose Test Strips. The Sejoy Advance Link Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertips. The Sejoy Advance Link Blood Glucose Monitoring System is intended for self-testing outside the body (in-vitro diagnostic use), by individuals with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended to be used by a single person and should not be shared. The system should not be used for the diagnosis of, or screening for diabetes or for neonatal use.

Device Description Summary

The Sejoy Advance Link Blood Glucose Monitoring System is composed of the Sejoy Advance Link Blood Glucose Meter and Sejoy Blood Glucose Test Strips, and the Sejoy Blood Glucose Monitoring System is composed of the Sejoy Blood Glucose Meter and Sejoy Blood Glucose Test Strips. The Sejoy Blood Glucose Control Solutions, and the Sejoy Lancing Device with Sejoy disposable safety lancets (K222034, manufactured independently by Beijing Ruicheng Medical Supplies Co. Ltd. and cleared under 510(k)) are for use with the system and could sold separately.

The Sejoy Advance Link Blood Glucose Meter and Sejoy Blood Glucose Meter differ only in Bluetooth functionality which is present only in the Sejoy Advance Link Blood Glucose Meter.

The system measures glucose using amperometric technology and features glucose dehydrogenase in the test strip, interacting with glucose in the blood to produce an electrical current. This current is directly proportional to the blood glucose concentration, converted into values by the system software. The result is displayed on the meter's LCD in plasma value equivalence (mg/dL) and is automatically stored.

The following items are included with the system, and are also sold separately:

- Sejoy Blood Glucose Control Solutions (CTRL1, CTRL2, and CTRL3)

- Sejoy Lancing Device and Sejoy Disposable Safety Lancets (K222034)

Comparison to Predicate Device:

Specifications and Features	**Predicate Device**	**Subject Devices**	
	OneTouch Verio Reflect Glucose Monitoring System (K193475)	**Sejoy** Blood Glucose Monitoring Systems	**Sejoy Advance Link** Blood Glucose Monitoring Systems
Intended Use/Indication for use	It is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. It is intended for self-testing outside the body (in-vitro diagnostic use), by individuals with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended to be used by a single person and should not be shared. The system should not be used for the diagnosis of, or screening for diabetes or for neonatal use.	Same	
Scientific Technology	Amperometric detection	Same	
Operating Principle	Electrochemical reaction with GDH-FAD Glucose Dehydrogenase	Same	
Calibration	Plasma-equivalent	Same	
Sample Site	Fingertip only	Same	
Sample Type	Capillary	Same	
Sample Volume	Minimum 0.4 ul	Minimum 0.6 ul	
Test Time	5 seconds	Same	
Glucose Measurement Range	20 - 600 mg/dL (1.1 - 33.3 mmol/L)	Same	
Hematocrit Range	20-60%	15-60%	
Operating Environment	6℃–44℃(43℉–111℉) and 10%-90%, non condensing	41℉–113℉(5℃–45℃) and 10~90% relative humidity	

Specifications and Features	Predicate Device	Subject Devices	
	OneTouch Verio Reflect Glucose Monitoring System (K193475)	**Sejoy** Blood Glucose Monitoring Systems	**Sejoy Advance Link** Blood Glucose Monitoring Systems
Test Strip Storage (Unopened Vial)	22 months 5°C – 30°C (41°F – 86°F) up to 65% RH	24 months 33.8°F~86°F (1°C~30°C) and 10~90% relative humidity	
Test Strip Storage (Opened Vial)	6 months from first opening	Same	
Coding	No calibration code is required	Same	
Data Download	Via USB or Bluetooth	Bluetooth Low Energy (Sejoy Advance Link only)	
Compatible off-meter software accessories	OneTouch Reveal	None	
Power source	2 x 3V CR2032	2 x AAA	
Meter Size (L x W x H)	Approx 3.97 x 1.69 x 0.61 inches	Approx 3.74 x 2.22 x 0.90 inches	
Weight	Approx 1.9 ounces	Approx 1.8 ounces	
User Interface Screen	Menu driven with text and icon based information.	Same	

Summary of Performance Characteristics

Sejoy Blood Glucose Monitoring System and Sejoy Advance Link Blood Glucose Monitoring System were designed and tested in accordance with FDA Guidance: Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use (September 2020). Analytical performance testing included repeatability, intermediate precision, hematocrit effect, short sample volume, perturbation, interference, and linearity testing. A user performance evaluation was also conducted in accordance with FDA Guidance: Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use (September 2020; Section VI.C) which assessed the accuracy of results

and usability of the device in the hands of intended users. SEJOY Blood Glucose Monitoring System and Sejoy Advance Link Blood Glucose Monitoring System performed similarly to both the predicate device as well as to a laboratory reference method, the Yellow Springs Instrument (YSI 2300 glucose analyzer).

User evaluation Comparison Study

A clinical (user evaluation) study was conducted with Sejoy Advance Link Blood Glucose Monitoring System. The Sejoy Advance Link Blood Glucose Meter and Sejoy Blood Glucose Meter differ only in Bluetooth functionality, and therefore this study also supports the accuracy of the Sejoy Blood Glucose Meter.The study comprised evaluating the system accuracy of the Sejoy Advance Link Blood Glucose Monitoring System by 352 lay persons representative of the age, gender, education of the intended users in the US that self-tested their capillary whole blood and compared to the YSI 2300 STAT PLUS glucose analyzer using capillary plasma.

Study results indicated that intended lay persons were able to obtain sufficiently accurate blood glucose readings when using the Sejoy Advance Link Blood Glucose Monitoring System compared to the laboratory-based comparator method. In addition, the participating lay persons were questioned and responded as satisfied with the ease of operation by following the Instructions for Use in the User Guide and the overall performance of the Sejoy Advance Link Blood Glucose Monitoring System. Users were able to achieve the following level of accuracy compared to the laboratory method:

Within ±5% n (%)	**Within ±10% n (%)**	**Within ±15% n (%)**	**Within ±20% n (%)**
200/352= 56.8%	318/352 = 90.3%	346/352 = 98.3%	352/352 = 100%

Accuracy at extreme glucose concentrations

A study was conducted to assess the accuracy of Sejoy Advance Link Blood Glucose Monitoring System at extremely low and high glucose levels using contrived capillary blood specimens. Among them, 50 subjects had low blood glucose (<80 mg/dL), and 50 had high blood glucose (>250 mg/dL). All blood glucose samples were unaltered. All samples were tested with the Sejoy Advance Link Blood Glucose Monitoring System using 3 test strips lots and compared to the results obtained on the comparator method (YSI 2300). Results are summarized below：

Sejoy Advance Link Blood Glucose Monitoring System for glucose concentrations <80 mg/dL			
Within +/- 5%	Within +/- 10%	Within +/- 15%	Within +/- 20%
27/50(54.0%)	46/50(92.0%)	50/50(100.0%)	50/50(100.0%)
Sejoy Advance Link Blood Glucose Monitoring System for glucose concentrations >250 mg/dL			
Within +/- 5%	Within +/- 10%	Within +/- 15%	Within +/- 20%
30/50(60.0%)	48/50(96.0%)	50/50(100.0%)	50/50(100.0%)

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence

Design verification and validation testing confirmed that the performance, safety, and effectiveness of the Sejoy Blood Glucose Monitoring Systemand and Sejoy Advance Link Blood Glucose Monitoring System were met against all design input specifications and the system can be considered substantially equivalent to that of the predicate device. Evaluations included repeatability, intermediate precision, and linearity. Sejoy Blood Glucose Monitoring System and Sejoy Advance Link Blood Glucose Monitoring System also meets the recommendations of FDA Guidance: Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use (September 2020), and applicable recognized electrical and safety standards including FCC requirements.

Conclusions

The proposed device is substantially equivalent in its intended use, performance, safety, effectiveness and underlying scientific and operating principles to the predicate, The OneTouch Verio Reflect Blood Glucose Monitoring System (K193475).