



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY AND INSTRUMENT**

**I Background Information:**

**A 510(k) Number**

K240640

**B Applicant**

Sejoy Biomedical Co., Ltd

**C Proprietary and Established Names**

Sejoy blood glucose monitoring system and Sejoy advance link blood glucose monitoring system

**D Regulatory Information**

Product Code(s)	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry

**II Submission/Device Overview:**

**A Purpose for Submission:**

New Devices

**B Measurand:**

Glucose in fingerstick capillary whole blood

**C Type of Test:**

Quantitative amperometry for blood, glucose dehydrogenase (FAD-GDH)

**III Intended Use/Indications for Use:**

**A Intended Use(s):**

See Indications for Use below.

## **B Indication(s) 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.

## **C Special Conditions for Use Statement(s):**

OTC - Over The Counter

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients.
- Not for use on critically ill patients, patients in shock or in a hyperglycemic-hyperosmolar state with or without ketosis.
- Not for neonatal use.
- Not for Alternative Site Testing (AST).
- Not for use with severe hypotension.
- Not for use with patients with severe dehydration.
- Not intended for diagnosis or screening of diabetes.
- Not for screening or diagnosis of diabetes mellitus.
- Do not use at altitudes above 10000ft (3048 meters) above sea level.
- Do not perform test during or soon after xylose absorption testing. High xylose level in the blood will cause inaccurate results.
- This meter is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities.
- Use of this meter on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

## **D Special Instrument Requirements:**

Sejoy Blood Glucose Meter

Sejoy Advance Link Blood Glucose Meter

## **IV Device/System Characteristics:**

### **A Device Description:**

Sejoy Blood Glucose Monitoring System consists of the Sejoy Blood Glucose Meter and the Sejoy Blood Glucose Test Strips and the Sejoy Advanced Link Blood Glucose Monitoring System consists of the Sejoy Advanced Link Blood Glucose Meter and the Sejoy Blood Glucose Test Strips. The test strips can be purchased in vials or individually wrapped foil packages.

The Sejoy Advanced Link Blood Glucose Meter uses Bluetooth to transmit glucose readings wirelessly to mobile devices to the Glucojoy App. Both meters have an optional voice feature that speaks certain messages such as the glucose results once testing is completed, announces when the battery is low, speaks the error codes if an error were to occur etc.

The Sejoy Blood Glucose Control Solutions (CTRL1, CTRL2, CTRL3), Sejoy Lancing Device (K222034) and Sejoy Disposable Safety Lancets (K222408) can be purchased separately for use with both systems.

### **B Principle of Operation:**

The Sejoy Blood Glucose Monitoring System and Sejoy Advance Link Blood Glucose Monitoring Systems quantitatively measure the amount of glucose in fresh capillary whole blood from the fingertip. Blood is applied to the end tip of the test strip and is then automatically pulled into the reaction cell through capillary action. The reaction area of the test strip includes the enzyme glucose dehydrogenase with cofactor flavin adenine dinucleotide (FAD-GDH) and mediator. Glucose in the sample reacts with the test strip chemistry to produce an electric current, which is proportional to the amount of glucose in the sample. The meter measures the strength of the current and displays the corresponding blood glucose concentration. The meter provides plasma-equivalent results.

### **C Instrument Description Information:**

#### **1. Instrument Name:**

Sejoy Blood Glucose Meter  
Sejoy Advance Link Blood Glucose Meter

#### **2. Specimen Identification:**

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

#### **3. Specimen Sampling and Handling:**

The glucose system is intended to be used with capillary whole blood from the finger only. The whole blood sample is applied directly to the test strip by capillary action.

4. Calibration:

The meter does not require calibration or coding by the user. The meter is automatically coded.

5. Quality Control:

Three levels of glucose control solutions (CTRL1, CTRL2, CTRL3) are available with this system and can be purchased separately. Recommendations on when to test the control materials are provided in the labeling. Acceptable ranges for each level of control solution are printed on the test strip vial label and test strip foil packet. If quality control test results are out of range, the user is advised to repeat the test. If problems continue, the user is cautioned not to use the meter and to contact the distributor. The Sejoy Blood Glucose Meter and Sejoy Advance Link Blood Glucose Meter recognize the control solutions automatically and do not store the control solution results.

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

**V Substantial Equivalence Information:**

**A Predicate Device Name(s):**

OneTouch Verio Reflect Blood Glucose Monitoring System

**B Predicate 510(k) Number(s):**

K193475

**C Comparison with Predicate(s):**

<b>Device &amp; Predicate Device(s):</b>	<u>K240640</u>	<u>K240640</u>	<u>K193475</u>
Device Trade Name	Sejoy Advance Link Blood Glucose Monitoring System	Sejoy Blood Glucose Monitoring System	OneTouch Verio Reflect Blood Glucose Monitoring System
<b>General Device Characteristic Similarities</b>			
Intended Use/Indications For Use	To be used for the quantitative measurement of glucose in fresh capillary whole	Same	Same

<b>Device &amp; Predicate Device(s):</b>	<u>K240640</u>	<u>K240640</u>	<u>K193475</u>
	blood drawn from the fingertips as an aid to monitor the effectiveness of diabetes control.		
Enzyme	Glucose Dehydrogenase	Same	Same
Measurement Range	20 - 600 mg/dL	Same	Same
<b>General Device Characteristic Differences</b>			
Sample Volume	Minimum 0.6ul	Minimum 0.6ul	Minimum 0.4ul
Hematocrit Range	15-60%	15-60%	20-60%
Data Transmission	Bluetooth	None	Via USB or Bluetooth

## VI Standards/Guidance Documents Referenced:

IEC 60601-1 Edition 3.2: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2 Edition 4.1: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

CLSI EP06 2<sup>nd</sup> Edition: Evaluation of the Linearity of Quantitative Measurement Procedures

CLSI EP07 3<sup>rd</sup> Edition: Interference Testing in Clinical Chemistry.

CLSI EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures

CLSI EP25-A Evaluation of Stability of In Vitro Diagnostic Reagents

ANSI AAMI SW96:2023 Standard for medical device security - Security risk management for device manufacturers

IEC 60601-1-11 Edition 2.1 2020-07 Consolidated Version: Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

## VII Performance Characteristics (if/when applicable):

The Sejoy Advance Link Blood Glucose Monitoring System was used as a representative model for the performance evaluations below to support both the Sejoy Advance Link Blood Glucose Monitoring System and the Sejoy Blood Glucose Monitoring System. The only difference between the systems is the presence of Bluetooth technology in the Sejoy Advance Link Blood Glucose Blood Glucose Meter, which does not impact the glucose measurement.

### A Analytical Performance:

#### 1. Precision/Reproducibility:

##### **Within-Run Precision (Repeatability)**

Within-run precision studies were performed using venous whole blood samples adjusted to 5 glucose concentration levels (30 to 50, 51 to 110, 111 to 150, 151 to 250, 251 to 400 mg/dL). Each sample was tested in replicates of 10 with 3 lots of test strips and 10 meters for a total of 300 tests per glucose level. Results are summarized below:

Glucose Level (mg/dL)	Strip Lot	N	Mean (mg/dL)	SD (mg/dL)	%CV
30 to 50	1	100	40.14	1.76	4.39%
	2	100	40.34	1.74	4.30%
	3	100	40.22	1.66	4.13%
	Combined	300	40.23	1.72	4.27%
51 to 110	1	100	90.11	2.71	3.00%
	2	100	90.10	2.88	3.19%
	3	100	90.02	2.52	2.80%
	Combined	300	90.08	2.70	2.99%
111 to 150	1	100	130.10	3.24	2.49%
	2	100	130.45	3.43	2.63%
	3	100	129.58	3.14	2.42%
	Combined	300	130.04	3.28	2.52%
151 to 250	1	100	205.18	5.09	2.48%
	2	100	204.49	4.40	2.15%
	3	100	205.01	4.91	2.39%
	Combined	300	204.89	4.80	2.34%
251 to 400	1	100	348.67	7.95	2.28%
	2	100	348.18	7.99	2.30%
	3	100	348.52	7.08	2.03%
	Combined	300	348.52	7.66	2.20%

## Intermediate Precision (Between Run)

Intermediate (between run) precision was evaluated using 5 levels of glucose control solutions (30 to 50, 51 to 110, 111 to 150, 151 to 250, 251 to 400 mg/dL) with 3 test strip lots and 10 meters. Each control solution level was measured once a day for 10 days with each meter and test strip lot, for a total of 100 replicates per control solution level per test strip lot for a total of 300 replicates for each glucose control solution level. Results are summarized below:

Glucose Level (mg/dL)	Strip Lot	N	Mean (mg/dL)	SD (mg/dL)	%CV
30 to 50	1	100	40.07	1.84	4.59%
	2	100	40.22	1.99	4.94%
	3	100	40.26	1.97	4.89%
	Combined	300	40.18	1.93	4.80%
51 to 110	1	100	92.2	3.09	3.35%
	2	100	91.63	2.67	2.92%
	3	100	92.1	3	3.26%
	Combined	300	91.98	2.93	3.18%
111 to 150	1	100	134.87	3.21	2.38%
	2	100	134.88	3.22	2.39%
	3	100	134.48	3.21	2.39%
	Combined	300	134.74	3.21	2.38%
151 to 250	1	100	195.47	4.83	2.47%
	2	100	195.39	4.64	2.38%
	3	100	195.01	4.73	2.42%
	Combined	300	195.29	4.72	2.42%
251 to 400	1	100	325.52	7.62	2.34%
	2	100	324.13	7.35	2.27%
	3	100	326.18	7.97	2.44%
	Combined	300	325.35	7.68	2.36%

## 2. Linearity:

The linearity was evaluated using venous whole blood samples adjusted to 11 glucose levels ranging from 17 to 619 mg/dL (17, 74, 139, 195, 253, 317, 382, 433, 492, 551 and 619 mg/dL as measured by comparator method YSI 2300 Analyzer) with 3 lots of test strips. Test procedures were performed in 4 replicates per lot per concentration level. Glucose results obtained using the Sejoy Advance Link Blood Glucose Monitoring System were compared to those obtained using comparator method YSI 2300 analyzer. The results of the regression analysis are:  $y = 1.0063x + 0.9607$ ;  $R^2 = 0.99667$ .

The results of the study support the sponsor's claimed glucose measuring range of 20 to 600 mg/dL. If a sample result is less than 20 mg/dL glucose, the result is flagged by the meter as "Lo". If a sample result exceeds 600 mg/dL glucose, the result is flagged by the meter as "Hi". The "Lo" and "Hi" functions were validated by the sponsor and were demonstrated to function as intended.

### 3. Analytical Specificity/Interference:

To assess potential interference, studies were performed by spiking 33 exogenous and endogenous substances into venous whole blood adjusted to three glucose levels (~60 mg/dL, ~125 mg/dL, and ~240 mg/dL). Each of these samples was divided into a test pool and a control pool, with the potential endogenous and exogenous interfering substances added to the test pool. The relative bias (mg/dL) and % bias between the test sample and the control sample was calculated using the mean of 10 replicates for each of 3 strip lots tested. The highest tested concentration for each substance at which no significant interference was observed (defined by the sponsor as less than  $\pm 10\%$ ) is summarized in the following table:

Test Substance	Highest concentration tested with no significant interference
Acetaminophen	20 mg/dL
Ascorbic acid	6 mg/dL
Cholesterol	625 mg/dL
Conjugated Bilirubin	50 mg/dL
Creatinine	15 mg/dL
Dopamine	0.09 mg/dL
EDTA	0.1 mg/dL
Galactose	60 mg/dL
Gentisic acid	1.8 mg/dL
Glipizide Tablets	0.1 mg/dL
Hemoglobin	1000 mg/dL
Heparin	300 IU/dL
Ibuprofen	50 mg/dL
Icodextrin	1094 mg/dL
Isomalt	0.09 mg/dL
Lactitol	0.09 mg/dL
L-DOPA	0.75 mg/dL
Maltitol	0.09 mg/dL
Maltose	900 mg/dL
Mannitol	1800 mg/dL
Metformin Hydrochloride Tablets	0.4 mg/dL
Methyldopa	2 mg/dL
Reduced Glutathione	4.6 mg/dL
Salicylic acid	60 mg/dL
Sodium chloride	180 mmol/L
Sorbitol	0.09 mg/dL



Test Substance	Highest concentration tested with no significant interference
Tolazamide	9 mg/dL
Tolbutamide	72 mg/dL
Triglyceride	1500 mg/dL
Unconjugated Bilirubin	40 mg/dL
Uric acid	23.5 mg/dL
Xylitol	0.09 mg/dL
Xylose	50 mg/dL

The sponsor includes the following statement in their labeling:

- Do not use during or soon after xylose absorption testing since xylose may cause inaccurate glucose results. Ask your doctor how long to wait before performing a glucose test.

4. Assay Reportable Range:

20 to 600 mg/dL glucose

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

**Traceability**

The glucose measurement functionality of the Sejoy Blood Glucose Monitoring System and Sejoy Advance Link Blood Glucose Monitoring System is traceable to the NIST SRM 917c glucose reference material. The method comparison/lay-user study was performed using the YSI 2300 STAT Plus Glucose Analyzer as the comparator method (see section VII.C.3).

**Test Strip Stability**

Test strip stability was assessed using real time stability and accelerated stability studies. Protocols and acceptance criteria were reviewed and found acceptable to support the labeling claims that the test strips are stable for 6 months after first being opened, and that closed vials and individual foil wrapped test strips are stable for 24 months when stored at the recommended storage temperatures 33.8°F - 86°F (1°C - 30°C) and 10 - 90% relative humidity. The labeling instructs the users not to freeze the test strips.

6. Detection Limit:

The reportable range is 20 to 600 mg/dL.

7. Assay Cut-Off:

Not applicable

8. Accuracy (Instrument):

Not applicable

9. Carry-Over:

Not applicable

**B Comparison Studies:**

1. Method Comparison with Predicate Device:

Please refer to lay user study below in section VII.C3.

2. Matrix Comparison:

Not applicable. The device is only intended for use with fresh capillary whole blood drawn from the fingertip.

**C Clinical Studies:**

1. Clinical Sensitivity:

Not applicable

2. Clinical Specificity:

Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

**Method Comparison/Lay User Performance Study**

To assess the performance of the Sejoy Blood Glucose Monitoring System and Sejoy Advanced Link Blood Glucose Monitoring System in the hands of the intended lay users, the sponsor conducted a study involving 352 lay user participants who collected and tested samples from their own fingertip using only the instructions from the product labeling in English. This study used the Sejoy Advanced Link Blood Glucose Monitoring System as the more complicated of the two candidate systems and 3 test strip lots. Results were analyzed by comparing blood glucose results obtained by the lay users with the Sejoy Advanced Link System against results obtained using a laboratory comparator method (YSI 2300 analyzer). Glucose concentrations in the samples ranged from approximately 64.2 to 491.5 mg/dL as measured by the comparator method, which included 45 unaltered samples below 80 mg/dL and 51 samples above 250 mg/dL. Results are summarized in the tables below:

Within $\pm$ 5%	Within $\pm$ 10%	Within $\pm$ 15%	Within $\pm$ 20%
200/352 (56.8%)	318/352 (90.3%)	346/352 (98.3%)	352/352 (100.0%)

Regression Analysis		
Slope	y-intercept	R <sup>2</sup> -value
1.024	1.204	0.987

### Usability

At the end of the lay-user study, each participant was asked to complete a usability questionnaire regarding ease of understanding of information in the user manual and the ease of use when performing a blood glucose test. The sponsor's analysis of the questionnaire responses demonstrated that the participants were satisfied with the ease of operation by following the instructions for use in the user's manual and with the overall performance of the Sejoy Advanced Link Blood Glucose Monitoring system.

### Labeling Readability

A Flesch-Kincaid readability assessment was conducted on the user's manual, test strip insert, and quick reference guide that demonstrated a readability level at an 8th grade level or lower.

### Extreme Glucose Study

An accuracy study was performed to evaluate the performance of the Sejoy Advanced Link Blood Glucose Monitoring System with 100 capillary blood samples containing extreme glucose concentrations at the extreme lower and upper ends of the claimed glucose measuring range. Glucose concentrations below 80 mg/dL were achieved with 50 samples altered by glycolysis and glucose concentrations greater than 250 mg/dL were achieved with 50 samples spiked with glucose. Results on the candidate device using 3 test strip lots were compared to the results obtained using the comparator method (YSI 2300 analyzer) and are summarized below:

Glucose Range	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Extreme Low (<80 mg/dL)	27/50 (54.0%)	46/50 (92.0%)	50/50 (100%)	50/50 (100%)
Extreme High (>250 mg/dL)	30/50 (60.0%)	48/50 (96.0%)	50/50 (100%)	50/50 (100%)

### D Clinical Cut-Off:

Not applicable.

### E Expected Values/Reference Range:

The sponsor includes the following expected blood glucose values for people without diabetes in the labeling:

- < 100 mg/dL fasting
- <140 mg/dL 2 hours after a meal

Reference: American Diabetes Association; Standards of Care in Diabetes-2023

## **F Other Supportive Instrument Performance Characteristics Data:**

### **1. Hematocrit Study**

The effect of different hematocrit levels was evaluated using venous whole blood samples with hematocrit levels of 15 to 60% (15%, 20%, 25%, 30%, 35%, 42%, 45%, 50%, 55%, and 60%) at 5 levels of glucose (30 – 50, 51 – 110, 111 – 150, 151 – 250, and 251 – 400 mg/dL). Each sample was tested in replicates of 10 using 3 test strip lots. The results obtained with the candidate system were compared to those obtained with the comparator method (YSI 2300 analyzer). The results demonstrated acceptable performance of the candidate blood glucose monitoring systems across the claimed hematocrit range of 15 to 60%.

### **2. System Operating Conditions Study**

To evaluate device performance over varying operating temperature and humidity conditions, venous whole blood samples were adjusted to 5 glucose levels (20-50, 51-110, 111-150, 151-250, and 251-600 mg/dL). There were four extreme temperature and humidity combinations tested (high temperature/low humidity 45°C/10%, low temperature/high humidity 5°C/90%, high temperature/high humidity 45°C/90%, and low temperature/low humidity 5°C/10%). The results obtained with the candidate system were compared to those obtained with the comparator method (YSI 2300 analyzer). The results support the claims in the labeling that the candidate blood glucose monitoring systems can be used in conditions of 41 to 113°F (5 to 45°C) with relative humidity of 10 to 90%.

### **3. Altitude Effects Study**

To evaluate the effects of altitude, a study was conducted using fingerstick whole blood samples altered to achieve 5 glucose concentrations ranging from 40.0 to 319.2 mg/dL. Each sample was tested using 3 test strip lots and 2 glucose in a pressurized chamber with corresponding pressure and oxygen content at 8 simulated altitudes from 0 to 11,482.9 ft. The results of obtained with the candidate system were compared to those obtained with the comparator method (YSI 2300 analyzer). The results support the claims that the candidate blood glucose monitoring systems function as intended at altitudes up to the claimed altitude of 10,000 feet.

### **4. Sample Volume Study**

Venous blood samples were prepared at 3 glucose range intervals (0-65 mg/dL, 100-120 mg/dL, and 200-250 mg/dL) and were tested at different sample volumes starting at 1.0 µL and incrementally decreased by 0.1 µL until an error code appeared. The results of obtained with the candidate system were compared to those obtained with the comparator method (YSI 2300 analyzer). The sponsor provided validation studies demonstrating that with blood volumes below 0.6 µL, the insufficient sample volume error message functioned as intended. The results support the claimed minimum sample volume of 0.6 µL for the candidate blood glucose monitoring systems.

### **5. Flex Studies**

The following additional flex studies were performed with the candidate system: drop/shock, early test strip removal, intermittent sampling, sample outside measuring range, sample perturbation, shipping, used test strips and vibration testing. The results demonstrated that the performance of the candidate blood glucose monitoring systems are robust under these conditions.

6. Electrical Safety and Electromagnetic Compatibility (EMC) Testing

The sponsor provided documentation certifying that acceptable electrical safety and (EMC) testing had been performed. The Sejoy blood glucose monitoring system was found to be compliant.

7. Infection Control Testing

The device systems are intended for single-patient use only. Disinfection efficacy studies were performed on the external meter materials by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, CaviWipes Disinfecting Towelettes (EPA Registration # 46781-17). A robustness study was also conducted by the sponsor demonstrating that there was no change in performance nor in the external materials of the meter after 4000 cleaning and disinfection cycles using the CaviWipes Disinfecting Towelettes. The robustness studies were designed to simulate 3 years of single-patient device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

8. Glucose Test Strip Lot Release Protocol

The test strip lot release protocol and criteria were reviewed and found to be acceptable.

**VIII Proposed Labeling:**

The labeling supports the finding of substantial equivalence for this device.

**IX Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.