



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

I Background Information:

A 510(k) Number

K250106

B Applicant

Signos, Inc.

C Proprietary and Established Names

Signos Glucose Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
SAF	Class II	21 CFR 862.1355 - Integrated Continuous Glucose Monitoring System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device

B Type of Test:

Quantitative, amperometric assay (Glucose Oxidase)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Signos Glucose Monitoring System is an over-the-counter (OTC) mobile device application that receives data from an integrated Continuous Glucose Monitor (iCGM) sensor and is intended to continuously measure, record, analyze, and display glucose values in people 18 years and older not on insulin. The Signos System helps to identify normal (euglycemic) and low or high (dysglycemic) glucose levels. The Signos System may also help the user better understand how lifestyle and behavior modification, including diet and exercise, impact glucose excursions. This information may be useful in helping users to maintain a healthy weight.

The user is not intended to take medical action based on the device output without consultation with a qualified healthcare professional.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

IV Device/System Characteristics:**A Device Description:**

Signos Glucose Monitoring System is a mobile device application that receives data from the Dexcom Stelo Biosensor iCGM and used to help people better understand their impact on their glucose results and how those glucose results impact other areas of their health.

The Signos Glucose Monitoring System consists of the smartphone application (on iOS or Android) and is paired with the Dexcom Stelo Glucose Biosensor System (distributed by Signos, Inc. upon payment and activation of the Signos Glucose Monitoring System). The application is obtained by downloading it from an App-Store (e.g. Google Play or Apple Store) and then activated by account setup with Signos, Inc.

Once activated, the Signos Glucose Monitoring System application functions as a primary display for a paired, off-the-shelf, Dexcom Stelo iCGM (K234070) by showing the user's glucose reading along with a historic trend. The Signos Glucose Monitoring System is not intended to be used by people on insulin.

The Signos Glucose Monitoring System includes several algorithms that analyze glucose values. These algorithms are variously intended to help identify euglycemic and dysglycemic glucose levels, and to help users better understand how lifestyle and behavior modification, including diet and exercise, impact glucose excursions. These algorithms are not intended to aid in the management of any disease.

B Instrument Description Information:**1. Instrument Name:**

Signos Glucose Monitoring System

2. Specimen Identification:

Not applicable

3. Specimen Sampling and Handling:

Not applicable

4. Calibration:

Not applicable to subject device. The Stelo Glucose Biosensor System (K234070) is factory calibrated.

5. Quality Control:

Not applicable

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):

Stelo Glucose Biosensor System

B Predicate 510(k) Number(s):

K234070

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K250106</u>	<u>K234070</u>
Device Trade Name	Signos Glucose Monitoring System	Stelo Glucose Biosensor System
General Device Characteristic Similarities		
Use Setting	Home use	Same
Intended Use Population	Persons who are not on insulin therapy age 18 years and older	Same
Type of Use	Over-the-counter use	Same
Displayed Range	70-250 mg/dL	Same

Display Device Update Interval	Every 15 minutes	Same
Glucose Alerts and Alarms	None	Same
General Device Characteristic Differences		
Sensor	Not included in clearance. Uses same sensor as cleared in predicate	Included in clearance.
Principle of Operation	Mobile device application displaying data Uses same sensor as cleared in predicate.	Mobile device application displaying data and biosensor: Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction

VI Standards/Guidance Documents Referenced:

None

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Previously established in K234070.

2. Linearity:

Previously established in K234070.

3. Analytical Specificity/Interference:

Previously established in K234070.

4. Accuracy (Instrument):

Not applicable.

5. Carry-Over:

Not Applicable.

B Other Supportive Instrument Performance Characteristics Data:

The following supportive performance characteristics were verified or validated through studies conducted on the subject device.

Human Factors

Eighteen participants enrolled in the study. Before entering the study session, participants completed a Health Assessment Questionnaire (HAQ). Fifteen of eighteen participants correctly self-selected as intended users. Participants representing intended users of the Product completed in-App onboarding, set-up the biosensor and paired it, logged meal and exercise information, and reviewed various App screens and answered questions about them.

Software Verification and Validation

Software verification and validation testing was conducted in accordance with established specifications and IEC 62304 and documentation was provided as recommended by FDA Guidance “Guidance for the Content of Premarket Submissions for Device Software Functions,” June 14, 2023. The test results for the Signos Glucose Monitoring System met acceptance criteria and are acceptable for their intended use.

Cybersecurity

Signos has provided cybersecurity risk management documentation for the Signos Glucose Monitoring System that includes analysis of confidentiality, integrity, and availability for data, information and software related to the Signos Glucose Monitoring System in accordance with the FDA Guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions” (September 27, 2023). For each identified threat and vulnerability risk event scenario, risk assessment of impact to confidentiality, integrity, and availability was performed and documented within the cybersecurity risk management documentation. Appropriate risk mitigation controls have been implemented and tested. In addition, Signos has controls and processes in place to ensure continued support for keeping the device secure and to ensure that the device firmware, software and components are malware free.

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.