

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

A. 510(k) Number:

k073638

B. Purpose for Submission:

Modification of a cleared device (addition of alternate site testing).

C. Measurand:

Whole blood glucose

D. Type of Test:

Whole Blood Glucose Concentration through a Quantitative Amperometric Assay (Glucose Oxidase)

E. Applicant:

Apex Biotechnology Corp.

F. Proprietary and Established Names:

GlucoSure Star Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1345, Glucose Test System
2. Classification:
Class II
3. Product code:
NBW, CGA
4. Panel:
75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):
See indications for use below.
2. Indication(s) for use:
The GlucoSure Star Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood taken from fingertips, palm, or forearm. Testing is done outside the body (in vitro diagnostic use). The GlucoSure Star System is plasma-calibrated for easy comparison to lab results. It is indicated for both lay use by people with diabetes and in a clinical setting by healthcare professionals, as an aid to monitoring levels in Diabetes Mellitus.

3. Special conditions for use statement(s):
 - Not for neonatal use
 - Not for screening or diagnosis of diabetes mellitus
 - Alternative site testing is for use at times of steady state only
 - For Over-the-Counter use
 - Not for use in critically ill patients or those in hyperosmolar state
4. Special instrument requirements:
 GlucoSure Star Blood Glucose Monitoring System

I. Device Description:

The GlucoSure Star Blood Glucose Monitoring System is based on an electrochemical biosensor technology (electrochemical) and the principle of capillary action. Capillary action at the end of the test strip draws the blood into the action chamber and the blood glucose result is displayed in 6 seconds. The control solutions available are used to test the performance of the device.

J. Substantial Equivalence Information:

1. Predicate device name(s):
 Apex Biotechnology Corp. GlucoTrack Blood Glucose Monitoring System.
2. Predicate 510(k) number(s):
 k062799
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	Glucose Oxidase
Test Range	20 – 600 mg/dL	20 – 600 mg/dL
Volume Required	1 µL	1 µL
Hematocrit Range	30-55%	30-55%
Test Time	6 seconds	6 seconds

Differences		
Item	Device	Predicate
Alternate Site Testing	Yes	No

K. Standard/Guidance Document Referenced (if applicable):

ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

L. Test Principle:

Glucose measurement is based on electrical potential caused by the reaction of glucose with the reagents contained on the strip’s electrodes. The glucose in the sample is oxidized by the enzyme glucose oxidase, and the current resulting from this enzymatic reaction is measured

and converted to glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The sponsor evaluated precision in k062799. The sponsor evaluated the precision of the device using replicate measurements of glucose adjusted venous whole blood with 3 different strip lots. Within-run precision was performed using ten replicates each of 5 glucose concentrations and 2 levels of glucose control solutions. Between-run precision was performed using ten replicates per day of 5 glucose concentrations and 2 levels of glucose control solutions for ten days were tested on ten meters each tested with 3 strip lots. Results are summarized in k062799.

b. *Linearity/assay reportable range:*

Linearity was established in the predicate device (k062799) and the study is summarized below:

To establish the linearity of the system whole blood samples were compared to YSI 2300 with three lots of test strips using 8 different glucose concentrations. For each lot of test strips, 10 meters were tested for each concentration. Linear regression yields the following statistics:

	Slope	y-intercept	r ²
Strip Lot 1	0.9894	-1.758	0.997
Strip Lot 2	1.007	-0.761	0.997
Strip Lot 3	1.028	-2.842	0.996

The sponsor claims 20 mg/dL as the lowest detectable limit in the labeling.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The controls were evaluated in the predicate device (k062799). The evaluation of the controls in that submission is described below.

The device is traceable to a laboratory analyzer which is calibrated to a glucose standard (NIST SRM 965a).

Stability characteristics of both levels of control solutions were determined using real time aging studies to determine the open vial storage stability at room temperature to be 18 months and unopened vial stability to be 24 months.

The expected values for the two glucose control solutions were established by repeat testing (10 times) on two meters using one lot of strips for both glucose levels. The expected results may change with each new lot, but the control range is listed on the control solution vials.

d. *Detection limit:*

The measuring range of the GlucoSure Star Blood Glucose Monitoring System is 20 - 600 mg/dL. This range was verified by the linearity study (above).

e. *Analytical specificity:*

Analytical specificity was evaluated in the predicate device (k062799).

f. *Assay cut-off:*

Not Applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

A consumer study was performed with 152 lay-users and a technician to see if glucose readings from the fingertip were comparable to a laboratory glucose reference method and that alternate site testing were comparable to fingertip. The labeling provided to the users was in English only. Each participant obtained their own alternate site samples and tested their blood using the instructions in the user's manual. The samples ranged from 44.7 – 454 mg/dL. For the palm site, both thenar and hypothenar sections were tested and found to give equivalent results when compared to each other. Results of the study are summarized below using single finger stick values:

Patient	Technician Fingerstick vs. YSI	Patient Palm vs. Technician FingerStick	Patient Forearm vs. Technician FingerStick
Samples < 75 mg/dL within ±15 mg/dL YSI	8/8 (100%)	8/8 (100%)	8/8 (100%)
Samples ≥ 75 mg/dL within ± 20% YSI	144/144 (100%)	143/144 (99%)	144/144 (100%)
Total	152/152 (100%)	151/152 (99%)	152/152 (100%)

Technician	Technician Fingerstick vs. YSI	Technician Palm vs. Technician FingerStick	Technician Forearm vs. Technician FingerStick
Samples < 75 mg/dL within ±15 mg/dL YSI	8/8 (100%)	8/8 (100%)	8/8 (100%)

Technician	Technician Fingerstick vs. YSI	Technician Palm vs. Technician FingerStick	Technician Forearm vs. Technician FingerStick
Samples \geq 75 mg/dL within \pm 20% YSI	144/144 (100%)	144/144 (100%)	144/144 (100%)
Total	152/152 (100%)	152/152 (100%)	152/152 (100%)

b. Matrix comparison:

Not applicable. Capillary whole blood is the only indicated matrix.

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable.

b. Clinical specificity:

Not Applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

The sponsor provided a readability study that indicated that the user manual, test strip labeling, and control solution labeling is at an 8th grade reading level or below.

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

The sponsor included the following Expected Values for normal glucose levels in their strip labeling:

74~106 mg/dL before meals¹

Less than 140 mg/dL two hours after meal²

1. Stedman, Thomas Lathrop. Stedman's Medical Dictionary, 27th Edition, 1999, pg. 2092.

2. American Diabetes Association, "Clinical Practice Recommendations 2003." Diabetes Care, Vol 26, Supplement 1, pg. S22.

N. Instrument Name:

GlucoSure Star Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional readings.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes or No

3. Specimen Identification:

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

4. Specimen Sampling and Handling:

This device is intended to be used with capillary whole blood from the finger, palm, or forearm only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

A code strip is provided with each batch of test strips to calibrate the meter for that batch. No further calibrations are required of the user.

6. Quality Control:

The sponsor is providing a single level glucose control solution with this device as a "starter kit." There is a "simple kit" in which controls are not provided. Two levels are available for purchase separately, as stated in the labeling. When a test strip is inserted into the meter, a control can be run. An acceptable range for each control level is printed on the control solution vial label. The user is referred to a troubleshooting section of the owner's manual to identify possible reasons control results fall outside these ranges.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

None

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

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