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

I Background Information:

A 510(k) Number

K212140

B Applicant

Apex Biotechnology Corp.

C Proprietary and Established Names

GlucoSure 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:

Modification to an existing device, which includes the addition of the Bluetooth Low Energy (BLE) functionality, addition of Bluetooth associated error messages, the removal of the voice feature and associated language and volume settings.

B Measurand:

Glucose in capillary whole blood from fingertip, palm, or forearm.

C 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 GlucoSure Link Blood Glucose Monitoring System is comprised of GlucoSure Link Blood Glucose Meter and GlucoSure Link Blood Glucose Test Strips.

The GlucoSure Link Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). This system is intended for self-testing (outside the body, or In Vitro Diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of your diabetes control and should only be used by a single patient and not be shared. It is not intended to be used for the diagnosis or screening of diabetes or for use on neonates.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

- Inaccurate results may occur in
  - Severe hypotensive individuals
  - Patients in shock
  - In a hyperglycemic-hyperosmolar state with or without ketosis
- Do not use on critically ill patients.
- Do not use on neonates.
- Do not use the system above 10335 feet (3,150 meters) in altitude.
- Severe dehydration (excessive water loss) may cause inaccurate results.
- For In Vitro Diagnostic use only.
- For single-patient use only.
- Perform Alternative Site Testing (AST) only if your glucose level is not changing rapidly.
- Do not use AST measurements to calibrate Continuous Glucose Monitors (CGMs).
- Do not use AST measurements for insulin dosing calculations.
- Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.
- This system has been demonstrated to function accurately with blood samples containing hematocrit of 30-55%. If you have certain conditions that may lead to high or low hematocrit (such as anemia, significant recent blood loss, severe dehydration etc.) the results from this system may not be accurate. If you are unsure, you should ask you healthcare professional.

D Special Instrument Requirements:

GlucoSure Link Blood Glucose meter

IV Device/System Characteristics:

A Device Description:

The GlucoSure Link blood glucose monitoring system (model number BGM024) consists of the GlucoSure Link meter, GlucoSure Link Blood Glucose Test Strips and Contrex Plus glucose control solutions (Level 1, Level 2, and Level 3). The GlucoSure Link Blood Glucose Test Strips and Contrex Plus glucose control solution are available for purchase separately.

B Principle of Operation:

The GlucoSure Link blood glucose monitoring system quantitatively measures glucose amperometrically, using test strips containing an enzyme (Glucose Oxidase). Glucose in the whole blood sample applied to the test strip reacts with the glucose oxidase. The electrons generated during this reaction are detected by the meter. The meter applies a small electrical current to the test strip and measures changes in the current caused by the reaction of glucose in the blood sample to the enzyme in the test strip. The magnitude of the resultant current is proportional to the concentration of glucose in the blood and is converted to a glucose concentration. The glucose concentration is displayed on the meter's display. The test results are plasma-calibrated.

C Instrument Description Information:

1. Instrument Name:

   GlucoSure 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 system is intended to be used with capillary whole blood samples drawn from the fingertips, forearm, or palm. The whole blood sample is applied directly to the test strip by capillary action and samples are to be tested immediately upon collection.

4. Calibration:

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

5. Quality Control:

   Contrex Plus Glucose Control Solutions (Level 1, Level 2, and Level 3) are available for use with the system. Each test strip vial is printed with a control solution range, and the user is

instructed to compare the control results with the expected control ranges printed on the strip vial. Users are given instructions on when to conduct control solution testing and to call customer service if repeat testing with control material is out of range.

V Substantial Equivalence Information:

A Predicate Device Name(s):

AutoSure Voice II Blood Glucose Monitoring System

B Predicate 510(k) Number(s):

K102037

C Comparison with Predicate(s):

Device & Predicate Device(s):	K212140	K102037
Device Trade Name	GlucoSure Link Blood Glucose Monitoring System	AutoSure Voice II Blood Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	Quantitative measurement of glucose in fresh capillary whole blood taken from fingertips, forearm or palm. This system is intended for self-testing (outside the body, or In Vitro Diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of your diabetes control.	Same
General Device Characteristic Differences		
Bluetooth	With	Without
Voice feature	Without	With

VI Standards/Guidance Documents Referenced:

CLSI EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition

IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

A within-run precision study using 3 lots of GlucoSure Link Blood Glucose test strips was performed. Venous blood was spiked to 5 concentrations (i.e., Level 1: 30-50 mg/dL, Level 2: 51-110 mg/dL, Level 3: 111-150 mg/dL, Level 4: 151-250 mg/dL, and Level 5: 251-400 mg/dL). For each sample concentration, 10 GlucoSure Link Blood Glucose meters were used, with 10 measurements taken by each meter for a total of 300 test for each glucose level. Results are summarized below:

Control Levels	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
L1	300	46	2.6	5.6
L2	300	89	3.0	3.3
L3	300	120	3.5	2.9
L4	300	221	5.1	2.3
L5	300	328	5.1	1.6

Intermediate precision was evaluated using 3 lots of the GlucoSure Link Blood Glucose test strips and five levels of control solutions (i.e., Level 1: 30-50 mg/dL, Level 2: 51-110 mg/dL, Level 3: 111-150 mg/dL, Level 4: 151-250 mg/dL, and Level 5: 251-400 mg/dL). Each sample was measured in replicates of 10 using 10 GlucoSure Link Blood Glucose meters over ten days resulting in a total of 300 tests for each glucose level. Results are summarized below:

Control Levels	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
L1	300	40	1.6	3.9%
L2	300	69	2.0	2.9%
L3	300	121	2.0	1.7%
L4	300	222	2.2	1.0%
L5	300	329	2.7	0.8%

2. Linearity:

Linearity was evaluated using venous whole blood adjusted to eleven glucose levels at 19.7, 50.1, 80.7, 115, 160, 200, 260, 310, 420, 530, and 610 mg/dL (as measured by the comparator method, YSI 2300) and 3 GlucoSure Link Blood Glucose test strip lots. The GlucoSure Link Blood Glucose Monitoring System results were compared with the values obtained from the comparator method. The results from the regression analysis are summarized below:

Lot 1: y = 0.9972x-0.1961, R2=0.9985
Lot 2: y = 1.0035x-1.0736, R2=0.9984
Lot 3: y = 1.0027x-0.8429, R2=0.9983

The results of the study support the sponsor's claimed glucose measurement range of 20 to 600 mg/dL. If a sample is less than 20 mg/dL, the result is flagged by the meter as "LO". If a sample result is more than 600 mg/dL, the result is flagged by the meter as "HI". The low and high functions were validated and demonstrated to function as intended.

3. Analytical Specificity/Interference:

Interference testing was conducted to evaluate the effect of endogenous substances and common exogenous substances expected in the intended use population on the GlucoSure Link Blood Glucose Monitoring System. The study was designed using venous whole blood samples adjusted to 3 target glucose levels (50-70 mg/dL, 110-130 mg/dL, and 225-270 mg/dL). Samples were divided into a test pool with the potential interferent added and a control sample with no added interferent. The difference between the test and control sample results was calculated and the concentration at which no significant interference (defined as average % bias ≤ 10%) was observed is listed in the table below:

Substances	Highest concentration at which no significant interference is observed	Substances	Highest concentration at which no significant interference is observed
Acetaminophen	10 mg/dL	Mannitol	1800 mg/dL
Ascorbic acid	6.0 mg/dL	Methyl-Dopa	2 mg/dL
Conjugated Bilirubin	25 mg/dL	Salicylic acid	60 mg/dL
Unconjugated Bilirubin	40 mg/dL	Sodium	180 mmol/L
Cholesterol	500 mg/dL	Tolbutamide	72 mg/dL
Creatinine	15 mg/dL	Tolazamide	9 mg/dL
Dopamine	0.09 mg/dL	Triglyceride	1500 mg/dL
EDTA	0.1 mg/dL	Uric Acid	15 mg/dL
Galactose	60 mg/dL	Xylose	600 mg/dL

Substances	Highest concentration at which no significant interference is observed	Substances	Highest concentration at which no significant interference is observed
Gentisic acid	1.8 mg/dL	Sorbitol	0.09 mg/dL
Reduced Glutathione	4.6 mg/dL	Xylitol	0.09 mg/dL
Hemoglobin	1000 mg/dL	Lactitol	0.09 mg/dL
Heparin	300 IU/dL	Isomalt	0.09 mg/dL
Ibuprofen	50 mg/dL	Maltitol	0.09 mg/dL
L-DOPA	0.75 mg/dL	Paralidoxime Iodide (PAM)	800 mg/dL
Maltose	480 mg/dL	Icodextrin	1094 mg/dL

The following statements are listed in the product labeling:

- If you are taking acetaminophen or acetaminophen containing drugs (for example Tylenol; at blood concentrations > 10 mg/dL) you may get inaccurate results with this system. If you are unsure, then ask your doctor.
- If you have certain conditions that may cause your blood level of uric acid to rise (> 15 mg/dL in your blood), such as gout or kidney disease, then your blood glucose results may be inaccurate with this meter. If you are unsure, then ask your doctor.

4. Assay Reportable Range:

The assay reportable range of 20-600 mg/dL is supported by the linearity study above (section VII.A.2).

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

Traceability:

The system reports plasma-equivalent glucose values, and is calibrated by using the YSI 2300 Glucose Analyzer, which is traceable to the NIST SRM 917c glucose reference material.

Test Strip Stability:

Test strip stability was assessed using real time stability studies. Protocols and acceptance criteria were reviewed and found acceptable and support the labeling claims that the GlucoSure Link Blood Glucose Test Strips are stable for 6 months after opening and 21 months unopened when stored between 39°F to 86°F (4°C to 30°C) and 10-85% relative humidity.

6. Detection Limit:

   See the linearity study above, section VII.A.2.

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:

   See Lay-user study below, Section VII.C.3.

2. Matrix Comparison:

   Not applicable.

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/User Evaluation study:

   To assess the performance of the GlucoSure Link Blood Glucose Monitoring System in the hands of the intended users, the sponsor conducted a user evaluation study consisting of 350 lay user participants who tested fingertip, palm and forearm capillary samples. Participants independently self-tested following only the product labeling in English. Three GlucoSure Link Blood Glucose test strip lots were used in the study. The results were analyzed by comparing the capillary blood glucose values obtained by the lay users to results obtained on the comparator method (YSI Model 2300 Glucose Analyzer). For fingerstick, palm and forearm samples, the glucose concentrations across all samples ranged from 63 to 485 mg/dL, which includes 40 native samples < 80 mg/dL and 251 samples > 250 mg/dL as

measured by the comparator method. All samples were native patient samples. The results are summarized below:

Accuracy Results for Entire Glucose range				
Site	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Fingertip	157 / 350 (44.9%)	318 / 350 (90.8%)	349 / 350 (99.7%)	350 / 350 (100%)
Palm	154 / 350 (44.0%)	290 / 350 (82.9%)	350 / 350 (100%)	350 / 350 (100%)
Forearm	161 / 350 (46.0%)	295 / 350 (84.3%)	350 / 350 (100%)	350 / 350 (100%)

Accuracy for blood glucose level <75mg/dL				
Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 20 mg/dL
Fingertip	10/13 (76.9%)	12/13 (92.3%)	13/13 (100%)	13/13 (100%)
Palm	6/11 (54.5%)	9/11 (81.8%)	11/11 (100%)	11/11 (100%)
Forearm	5/11 (45%)	7/11 (63.6%)	11/11 (100%)	11/11 (100%)

Accuracy for blood glucose level ≥75mg/dL				
Site	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Fingertip	147/337 (43.7%)	306/337 (90.9%)	336/337 (99.4%)	337/337 (100%)
Palm	148/339 (44%)	281/339 (82.9%)	339/339 (100%)	339/339 (100%)
Forearm	156/339 (46%)	288/339 (84.3%)	339/339 (100%)	339/339 (100%)

Regression analysis results for each anatomical site:	
Fingertip	$y = 0.9865x + 2.9608$, $R^2 = 0.9725$
Palm	$y = 0.9923x + 1.5084$, $R^2 = 0.9708$
Forearm	$y = 0.9918x + 1.7052$, $R^2 = 0.9717$

Accuracy at Extreme Glucose Study:

A study to evaluate the performance of the GlucoSure Link Blood Glucose Monitoring System in the extreme lower and upper ends of the claimed range was performed using 50 altered samples with glucose concentrations below 80 mg/dL, and 50 samples greater than 250 mg/dL. Samples were altered by spiking or glycolysis in order to obtain the appropriate glucose concentrations. Samples were tested using 3 lots of the GlucoSure Link Blood Glucose Test Strips and were compared to the results obtained on the YSI 2300 analyzer. The glucose concentrations in the samples ranged from 20-79 mg/dL on the lower end and 262-600 mg/dL on the higher end, as measured by the YSI 2300. Results are summarized below:

Glucose concentrations <80 mg/dL:

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
22/50 (44.0%)	42/50 (84.0%)	50/50 (100.0%)	50/50 (100.0%)

Glucose concentrations >250mg/dL:

Within ± 5%	Within ± 10%	Within ±15%	Within ± 20%
15/50 (30.0%)	30/50 (60.0%)	50/50 (100.0%)	50/50 (100.0%)

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 results demonstrated that the participants were able to understand the labeling and conduct the testing on their own.

Readability:

A Flesch-Kincaid readability assessment was conducted, and the results demonstrated that the GlucoSure Link Blood Glucose Monitoring System's instructions for use are written for a reading level lower than 8th grade.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Based on published literature, the sponsor included the following in the labeling:

The ideal ranges for adults without diabetes are (*):

- less than 100 mg/dL before meals.
- less than 140 mg/dL within 2 hours after a meal.

*American Diabetes Association, Standard of Medical Care in Diabetes 2020, Vol. 43 (Suppl. 1).

F Other Supportive Instrument Performance Characteristics Data:

1) System operating conditions (temperature, humidity):

   The GlucoSure Link Blood Glucose Monitoring System was tested at different temperature and humidity conditions to assess the effect of the operation environment on the performance of the system. Temperatures ranging from 50 - 104°F (10 - 40°C) and 20 –85% relative humidity were tested. Five temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, high temperature/low humidity and high temperature/high humidity. Venous whole blood glucose levels (60, 120, 200, and 400 mg/dL) were tested using 10 meters and 3 lots of GlucoSure Link Blood Glucose test strips. Values measured by the GlucoSure Link Blood Glucose Monitoring System were compared to the results obtained using the comparator method, the YSI 2300 method. The study results support the labeled operating conditions claim of 50-104°F (10-40°C) and 20-85% RH.

2) Sample Volume Study:

   The sponsor performed a study to support the claimed minimum sample volume of 1.0 µL for the GlucoSure Link Blood Glucose Monitoring System. Venous whole blood samples with 3 glucose concentrations (50-65, 100-120 and 200-250 mg/dL) were tested at 5 sample volumes (0.8, 0.9, 1.0, 1.1 and 1.2 µL) using 3 lots of GlucoSure Link Blood Glucose test strips and 10 GlucoSure Link meters. Values obtained were compared to the results obtained using the comparator method (YSI 2300 Glucose analyzer). Results support the claimed minimum sample volume of 1.0 µL for the system. The meter displays an error message if enough blood is not added to the test strip. This feature was validated and was shown to function as intended.

3) Hematocrit Study:

   The effect of hematocrit on the performance of the GlucoSure Link Blood Glucose Monitoring System was evaluated at 30%, 35%, 42%, 50%, and 55% hematocrit levels, and at 5 glucose concentrations (30-50, 51-110, 111-150, 151-250 and 251-400 mg/dL). Each sample was tested in replicates of 10 using 10 meters and 3 lots of GlucoSure Link Blood Glucose test strips, for a total of 30 replicates per sample. The values were compared with the glucose measurements obtained using the comparator method (YSI 2300 Glucose analyzer). The results of the study demonstrated adequate performance to support the claimed hematocrit range of 30%-55%.

4) Altitude Study:

   A high-altitude study was conducted where the effects of sea level (<500 ft) and high-altitude (10,000 ft) were simulated and the effects on the GlucoSure Blood Glucose Monitoring System were evaluated. Venous whole blood samples adjusted to 5 glucose concentrations (50, 120, 220, 330, and 450 mg/dL) were tested using 10 meters and 3 lots of GlucoSure Link Blood Glucose test strips. Values measured by the candidate device were compared with the glucose measurements obtained with the comparator method (YSI 2300 Glucose analyzer). The results of the study support the claim that the

GlucoSure Blood Glucose Monitoring System can be operated at altitudes of up to 10,000 ft.

5) Flex Studies:

   Flex studies were performed demonstrating that the GlucoSure Link Blood Glucose Monitoring System is robust to short sample application, sample perturbation, testing with used test strips, intermittent sampling, drop and vibration.

6) Infection Control Studies:

   The device system is intended for single patient use. Disinfection efficacy studies were previously performed (k150396) with the external meter materials by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) or removal of HBsAg with the following disinfectants: Clorox Healthcare Bleach Germicidal and Disinfectant Wipes (EPA Registration Number: 67619-12), Dispatch Hospital Cleaner Disinfectant Towels with Bleach (EPA Registration Number: 56392-8), Medline Micro-Kill+ Disinfecting, Deodorizing, Cleaning Wipes with Alcohol (EPA Registration Number: 59894-10), and Medline Micro-Kill Bleach Germicidal Bleach Wipes (EPA Registration Number: 69687-1-37549). The sponsor also conducted robustness studies demonstrating that there was no change in performance or to the external materials of the meter after 260 cleaning and disinfection cycles (representing weekly disinfection for five years, the expected lifetime of the meter). Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7) The sponsor provided acceptable documentation certifying that acceptable electrical safety and electromagnetic compatibility (EMC) testing was performed with the candidate system and the system was found to be compliant.

8) Test strip lot release criteria: The test strip lot release protocols and criteria were reviewed and found to be acceptable.

VIII Proposed Labeling:

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

IX Conclusion:

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