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

A. 510(k) Number:

K170264

B. Purpose for Submission:

New Device

C. Measurand:

Glucose in fresh capillary whole blood obtained from the fingertip.

D. Type of Test:

Quantitative, amperometric method, glucose dehydrogenase (FAD-GDH)

E. Applicant:

Sinocare Meditech, Inc.

F. Proprietary and Established Names:

Gold AQ Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345, blood glucose test system

2. Classification:

   Class II

3. Product code:

   NBW, System, Test, Blood Glucose, Over the Counter

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use below.

2. Indication(s) for use:

   The Gold AQ Blood Glucose Monitoring System is designed for the quantitative measurement of glucose in fresh capillary whole blood from the fingertip. It is intended

to be used by people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program.

The Gold AQ Blood Glucose Monitoring System is comprised of the Gold AQ blood glucose meter and the Gold AQ blood glucose test strip. The Gold AQ Blood Glucose Monitoring System is for self-testing outside the body (in vitro diagnostic use).

The Gold AQ Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The Gold AQ Blood Glucose Monitoring System is not intended for the diagnosis of, or screening of diabetes. It is not intended for use on neonates.

3. Special conditions for use statement(s):

   For over-the-counter use.

   - Not for neonatal use.
   - Not for screening or diagnosis of diabetes mellitus.
   - For single patient use only (over-the-counter) and should not be shared.
   - Not for use on the critically ill.
   - Not for alternative site testing (AST) use.
   - For in vitro diagnostic use only.
   - Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
   - Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate results may also occur in individuals experiencing a hyperosmolar-hyperglycemic- state (HHS).
   - Hematocrit beyond 20%~70% can cause false reading. Ask your doctor if you do not know your hematocrit.
   - This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities, including for routine assisted testing or as part of glycemic control procedures. The Gold AQ Blood Glucose Monitoring system is intended to be used for patient self-monitoring. It should not be used to test blood from more than one person, as this poses a risk of transmitting blood-borne pathogens such as Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV) or other blood-borne pathogens.

4. Special instrument requirements:

   Gold AQ Blood Glucose Meter

I. Device Description:

The Gold AQ Blood Glucose Monitoring System consists of a hand-held, battery-powered Gold AQ Blood Glucose Meter; disposable Gold AQ Blood Glucose Test Strips; and Gold AQ Control Solution.

The Gold AQ Blood Glucose Test Strips are plastic strips that contain an electrochemical biosensor that fits into the meter. The test strip uses glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) based chemistry for the measurement of glucose in whole blood samples.

The Gold AQ Control solutions are aqueous solutions containg glucose and are available at three levels (level 1, level 2 and level 3).

The meter, test strips, glucose control solutions and lancing device are marketed within a single package (Kit), and each of these components are also available for purchase separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Contour Next Blood Glucose Monitoring System

2. Predicate 510(k) number(s):

   k121190

3. Comparison with predicate:

Item	**Predicate Device** Contour Next Blood Glucose Monitoring System (k121190)	**Candidate Devices** Gold AQ Blood Glucose Monitoring System (k170264)
Intended Use	It is intended to be used for quantitative measurement of glucose in whole blood for diabetes management.	Same
Reagent form	Electrochemical test strip	Same
Test Results	Plasma calibrated	Same
Use Setting	At home for single patient use	Same
Detection Method	Electrochemical biosensor	Same
Enzyme	FAD - Glucose dehydrogenase	Same

Item	**Predicate Device** Contour Next Blood Glucose Monitoring System (k121190)	**Candidate Devices** Gold AQ Blood Glucose Monitoring System (k170264)
Meter Memory Display	800 test results	500 blood glucose test results 100 control solution test results
Measuring Range	20 - 600 mg/dL	Same
Sample Type	Capillary whole blood	Same
Sample Sites	Fingertip or palm	Finger tip
Sample Volume	0.6 µL	0.8 µL
Sample Test Time	5 seconds	Same
Hematocrit range	15% - 65%	20% - 70%
Altitude	Up to 20,674 feet	Up to 10,100 feet
Identification of Control Solution and Results	Automatically distinguishes control solutions from whole blood samples	Same
Power Source	Two 3-volt lithium batteries (DL2032 or CR2032)	2 AAA alkaline batteries
Coding	No coding	Same

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

ISO 14971 Medical devices - Application of risk management to medical devices.

IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirement for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

IEC61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements.

IEC 61326 Electrical equipment for measurement, control and laboratory use - EMC requirements --Part 1: General Requirements.

IEC 62366 Medical devices - Application of usability engineering to medical devices.

ISO 15223 Medical devices - Symbols to be used with Medical Device labels, labeling, and information to be supplied - Part 1: General requirements.

CLSI EP06-A "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach"

L. Test Principle:

The glucose test is based on the measurement of electrical current caused by the reaction of glucose with the FAD glucose dehydrogenase enzyme on the electrode of the test strip. The blood or control solution sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with the FAD glucose dehydrogenase and generates electrons, which produce an electrical current. The Gold AQ blood glucose meter measures the electrical current and calculates the glucose result. The glucose result is displayed by the meter in the measurement unit of mg/dL.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The sponsor performed repeatability (within-day) precision studies using venous whole blood samples spiked to six different glucose concentration levels (30 to 50, 51 to 110, 111 to 150, 151 to 250, 251 to 400 and 401 to 600 mg/dL). Each glucose concentration level was analyzed in replicates of 10, with 3 test strip lots and 10 meters, for a total of 100 replicates per glucose level per test strip lot (for a total of 300 tests per each glucose level for 10 meter). Results are summarized below:

Lot 1				
Glucose Level (mg/dL)	Mean (mg/dL)	n	SD (mg/dL)	CV (%)
30 to 50	39.1	100	1.2	3.1
51 to 110	90.4	100	2.2	2.4
111 to 150	138.7	100	3.3	2.4
151 to 250	239.3	100	6.9	2.9
251 to 400	373.1	100	10.4	2.8
401 to 600	487.1	100	11.3	2.3

Lot 2				
Glucose Level (mg/dL)	Mean (mg/dL)	n	SD (mg/dL)	CV (%)
30 to 50	39.1	100	1.4	3.5
51 to 110	89.7	100	2.5	2.8
111 to 150	136.3	100	4.6	3.4
151 to 250	237.7	100	7.0	2.9
251 to 400	372.2	100	11.1	3.0
401 to 600	486.8	100	10.1	2.1

Lot 3				
Glucose Level (mg/dL)	Mean (mg/dL)	n	SD (mg/dL)	CV (%)
30 to 50	38.9	100	1.3	3.4
51 to 110	89.0	100	2.7	3.1
111 to 150	137.5	100	5.1	3.7
151 to 250	236.3	100	6.3	2.7
251 to 400	369.4	100	10.4	2.8
401 to 600	486.4	100	9.6	2.0

Intermediate (day to day) precision was evaluated using six levels of glucose control solutions (30 to 50, 51 to 110, 111 to 150, 151 to 250, 251 to 400 and 401 to 600 mg/dL) over 10 days with 3 test strip lots. For each level, on each day, 10 meters were used for testing, with 10 replicates collected per lot for a total of 30 replicates per 3 lots for each glucose level per day. Results are summarized below:

Lot 1			
Glucose Level (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV (%)
30 to 50	47.2	1.6	3.5
51 to 110	91.7	2.9	3.1
111 to 150	132.7	3.3	2.5
151 to 250	177.9	4.9	2.7
251 to 400	344.5	9.6	2.8
401 to 600	425.6	13.7	3.2

Lot 2			
Glucose Level (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV (%)
30 to 50	46.5	1.6	3.4
51 to 110	92.4	2.7	3.0
111 to 150	132.6	3.5	2.7
151 to 250	179.1	3.7	2.0
251 to 400	349.4	8.5	2.4
401 to 600	426.8	9.6	2.2

Lot 3			
Glucose Level (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV (%)
30 to 50	47.3	1.6	3.5
51 to 110	92.1	2.6	2.8

Lot 3			
Glucose Level (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV (%)
111 to 150	132.8	3.9	2.9
151 to 250	179.0	4.0	2.2
251 to 400	349.3	9.3	2.7
401 to 600	425.5	10.6	2.5

b. *Linearity/assay reportable range:*

Linearity testing was performed using Na-heparin venous whole blood samples. The evaluation was conducted with 15 meters and 3 test strip lots. Eleven samples with the following glucose concentrations (mg/dL) were prepared: 16.0, 76.0, 136, 194, 254, 313, 372, 433, 495, 548, 530.3, and 610 (as established using a laboratory comparator method (YSI 2300 analyzer)). Twenty strips from each lot tested on five meters were used for testing at each glucose concentration for a total of n=20 tests per glucose concentration per test strip lot (n=60 tests per glucose concentration). The evaluation yielded the following regression equation based on all samples:

Lot	Slope	y-intercept	R^2
1	0.9900	-0.0629	0.9992
2	0.9906	-0.1996	0.9998
3	0.9887	0.2410	0.9997

The results of the study support the sponsor's claimed glucose measuring range of 20-600 mg/dL. The meter displays "Lo" if test result is less than 20 mg/dL, and "Hi" if test result is more than 600 mg/dL. The "Lo" and "Hi" functions were validated and demonstrated to function as intended.

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

Traceability:

The system is traceable to the NIST SRM #917c glucose reference material. The method comparison study was performed using the candidate device and YSI as the comparator method (see Section 2.a. below).

Test Strip Stability:

Stability protocols and acceptance criteria for the Gold AQ Test Strips were reviewed and found to be acceptable to support closed-vial stability of 24 months and open-vial stability of six months when test strips are stored at 34°F to 86°F (1°C to 30°C), 10-90% relative humidity or until the expiration date printed on the label, whichever comes first. The labeling instructs the users not to freeze the test strips.

d. Detection limit:

See linearity study in Section M1b above.

e. Analytical specificity:

Interference studies were performed by spiking endogenous and exogenous substances (at zero, therapeutic and toxic concentrations) into venous whole blood. Each potential interferent was tested at three glucose levels (approximately 50-70, 110-130, and 250-350 mg/dL). Thirty replicates were measured for each test sample. Results of test samples with the potential interferent measured on the Gold AQ Blood Glucose Monitoring System were compared to samples with zero potential interferent measured on the Gold AQ Blood Glucose Monitoring System, and percent bias was calculated. This procedure was performed for three test strip lots using ten meters. The compounds at the concentrations listed below did not have significant interference (defined by the sponsor as percent bias between spiked sample glucose results and control sample glucose results is within ±10%):

Interfering substance	**Concentration with no Significant Interference**
Acetaminophen	20 mg/dL
Ascorbic acid	3 mg/dL
Cholesterol	600 mg/dL
Bilirubin, unconjugated	50 mg/dL
Bilirubin, conjugated	50 mg/dL
Creatinine	10 mg/dL
Dopamine HCl	24.8 mg/dL
EDTA	200 mg/dL
Galactose	15 mg/dL
Gentisic acid	60 mg/dL
Haemoglobin	20,000 mg/dL
Ibuprofen	50 mg/dL
Maltose	2000 mg/dL
Methyl-L-dopa	100 mg/dL
Salicylic acid	60 mg/dL
Sodium chloride	175 mEq/L
Tolazamide	100 mg/dL
Tolbutamide	100 mg/dL
Triglyceride	1500 mg/dL
Uric acid	10 mg/dL
Xylose	20 mg/dL
Heparin Sodium	5000 mg/dL
L-Dopa	0.5 mg/dL
Glutathione	92 mg/dL
Isomalt	100 mg/dL
Lactitol	100 mg/dL

Interfering substance	Concentration with no Significant Interference
Maltitol	100 mg/dL
Mannitol	800 mg/dL
Sorbitol	100 mg/dL
Xylitol	100 mg/dL

The sponsor list the following limitations in the device labeling:

- Uric acid at concentrations greater than 10 mg/dL interferes with the glucose measurements. If you have medical conditions that are associated with high uric acid levels or hyperuricemia (e.g. kidney disease or gout), then please check with your healthcare provider before using this device.
- If you are taking vitamin C (blood concentration of > 3.0 mg/dL ascorbic acid), then you may obtain inaccurate readings from this blood glucose monitoring system. Please check with your health care professional before using this device.
- Xylose at concentrations greater than 20 mg/dL interferes with glucose measurements from this device and may falsely raise glucose results. Do not use this device during or soon after a Xylose Absorption Test.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

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):

User Performance study:

To assess the performance of the Gold AQ Blood Glucose Monitoring System in the hands of the intended users, the sponsor performed a study with 105 lay user

participants who collected and tested samples from their own fingertip. Results were analyzed by comparing blood glucose results obtained by the lay users with the Gold AQ Blood Glucose Monitoring System against results obtained using a laboratory comparator method (YSI 2300 analyzer). Glucose concentrations in the samples ranged from approximately 46 to 464 mg/dL as measured by the laboratory reference method. Results are summarized in the tables below:

Regression Equation: y = 1.049x – 3.814

For glucose concentrations < 75 mg/dL		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
10/11 (90.9%)	11/11 (100%)	11/11 (100%)

For glucose concentrations ≥75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20 %
54/94 (57.4%)	80/94 (85.1%)	92/94 (97.9%)	93/94 (98.9%)

Human Factors/Usability/Readability Study:

A separate human factors/usability/readability study was performed where the participants performed a list of tasks related to the use of the candidate device using only the proposed device labeling. The participants completed the usability questionnaires regarding ease of use and the label comprehension questionnaires regarding ease of understanding of information in the user manual. The study demonstrated that users of the device were able to understand and follow the instructions provided in the labeling to perform tasks involved in blood glucose testing.

Flesch-Kincaid readability assessment was conducted on all labeling and demonstrated that the User Manuals for the Gold AQ blood glucose monitoring system are written at an 8th grade level or below.

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   The sponsor provided the following information for expected glucose values for persons without diabetes:

   The normal adult fasting blood glucose range for a nondiabetic person is in the range 70-100 mg/dL and less than 140 mg/dL up to 1-2 hours after meals.

   Source: American Diabetes Association, Diabetes Care 2017; 40 (Suppl. 1):S11-S24.

N. Instrument Name:

Gold AQ Blood Glucose Monitoring System.

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and requires a sample volume of 0.8 μL.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes _____ or No ___X_____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ___X_____

2. Software:

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

   Yes ____X____ 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:

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

5. Calibration:

   Calibration is automatic. There is no user input for coding.

6. Quality Control:

   Gold AQ Control solutions are aqueous solutions containg glucose and are available at three levels (level 1, level 2 and level 3). Instructions on how to order the control solutions are included in the user manual. The control solution readings are not included in the average of the patient results. An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. Hematocrit Study: To evaluate the effect of hematocrit on the Gold AQ blood glucose monitoring system, venous blood samples were adjusted to hematocrit levels of 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65% and 70%. Each hematocrit level was tested at five glucose concentration intervals (38, 75, 138, 215 and 345 mg/dL) for a total of 55 samples. Each sample was tested in replicates of ten using 10 meters and 3 test strip lots. Results from the meter were compared to results obtained using a laboratory-based comparator measurement (YSI 2300 analyzer). The evaluation of bias and percent bias relative to values obtained on the YSI 2300 analyzer demonstrate acceptable performance across the claimed hematocrit range of 20-70%.
2. Altitude study: To evaluate the effect of altitude on the Gold AQ blood glucose monitoring system, meters were tested at 26±16ft, 1312±20ft, 3205±30ft, 5348±30ft, 7343±26ft and 10,207 ft). Five glucose levels (approximately 31, 84, 230, 370 and 541 mg/dL) were tested at each altitude. The evaluation included testing each sample in ten replicates with three meters three test strip lots. Results were compared to results obtained using a laboratory-based comparator measurement (YSI 2300 analyzer) and demonstrated that altitudes from 26 to up to 10,207 feet above sea level have no significant effect on blood glucose measurements.
3. Sample Volume: To verify the minimum sample volume requirement, venous whole blood samples with four volumes (0.6, 0.7, 0.8 and 0.9 µL) were tested. Sample concentrations included three glucose levels (61, 113, and 243 mg/dL) tested at each volume. Values obtained with the candidate device were compared to values obtained using a laboratory-based comparator method (YSI 2300 analyzer). Results support the claimed minimum sample volume of 0.8 µL. The meter displays two error messages when insufficient sample volume is applied to the test strip. The sponsor provided validation studies demonstrating that these error features function as designed and intended.
4. Sample Perturbation: To evaluate system performance when sample is perturbed during testing, test strips were disturbed by shaking during the meter countdown after venous whole blood samples were applied to the test strips. The results demonstrate that perturbation of sample during the countdown process of sample testing does not significantly affect meter glucose results when compared to the comparator method (YSI 2300 analyzer) glucose results.
5. Intermittent Sampling: To evaluate system performance during intermittent sampling, venous whole blood samples were applied to the test strip intermittently during the meter countdown demonstrating that intermittent sampling during the countdown process of sample testing gives an error code when a short sample is initially applied to the test strip.

6. Test with Used Test Strips: A study was performed demonstrating that the Gold AQ BGMS displays an error when a used test strip is inserted in to the Gold AQ meter instead of displaying a glucose measurement result.
7. Control Auto-Detection Testing: A study was performed demonstrating that the Gold AQ meter automatically detects the three levels of Gold AQ control solutions and distinguishes them from the blood samples.
8. System Operating Conditions: To evaluate system performance under the extremes of the recommended temperature and humidity conditions, sample testing was performed at temperatures of 50ºF and 104ºF, and relative humidity (RH) of 10% and 90%. Testing was performed at each temperature (50 ºF and 104ºF) and each RH (10% and 90%) combination. The results obtained on the Gold AQ blood glucose monitoring system were compared to those obtained on the comparator method, YSI 2300, and support the claimed operating conditions of of 50ºF - 104ºF (10-40ºC) and RH of 10-90%.
9. Infection Control and Robustness Studies: The Gold AQ blood glucose monitoring system is intended for single-patient use. Disinfection efficacy testing on the surface materials of the meter demonstrated complete inactivation of duck hepatitis B virus (HBV) with the chosen disinfectant, Clorox Healthcare Bleach Germicidal Wipes (EPA Registration # 67619-12). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 260 cleaning and disinfection cycles (a total of 520 wipes) designed to simulate 5 years of single-patient use for the Gold AQ blood glucose monitoring system. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.
10. The sponsor provided appropriate documentation certifying that electromagnetic (EMC) testing was performed and the Gold AQ blood glucose monitoring system was found to be compliant.
11. The meter manual states that customer service is available (24 hours a day, 7 days a week) by calling 1-800-566-8558.

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.