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

I Background Information:

A 510(k) Number

K231476

B Applicant

Sinocare Inc.

C Proprietary and Established Names

TRUENESS™ AIR Blood Glucose Monitoring System; TRUENESS™ 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 device

B Measurand:

Glucose in capillary whole blood drawn from the fingertip

C Type of Test:

Quantitative amperometric assay (glucose dehydrogenase-FAD)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The TRUENESS™ Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger. It is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of their diabetes control program. The TRUENESS™ Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It is for in vitro diagnostic use only. The TRUENESS™ Blood Glucose Monitoring System is not intended for the diagnosis of, or screening for diabetes. It is not intended for use on neonates.

The TRUENESS™ Blood Glucose Monitoring System is comprised of the TRUENESS™ blood glucose meter and the TRUENESS™ blood glucose test strip.

The TRUENESS™ AIR Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in capillary whole blood from the finger. It is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of their diabetes control program. The TRUENESS™ AIR Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It is for in vitro diagnostic use only. The TRUENESS™ AIR Blood Glucose Monitoring System is not intended for the diagnosis of, or screening for diabetes. It is not intended for use on neonates.

The TRUENESS™ AIR Blood Glucose Monitoring System is comprised of the TRUENESS™ AIR blood glucose meter and the TRUENESS™ blood glucose test strip.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

- For in vitro diagnostic use only
- For self-testing
- Not for use on critically ill
- Not for neonatal use
- Not for screening or diagnosis of diabetes mellitus
- Not for alternative site testing (AST) use.
- Xylose: Do not perform test during or soon after xylose absorption testing. High xylose level in the blood will cause inaccurate results
- 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)
- For single patient use only and should not be shared

- 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 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. 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 blood borne pathogens

D Special Instrument Requirements:

Trueness Blood Glucose Meter
Trueness Air Blood Glucose Meter

IV Device/System Characteristics:

A Device Description:

The TRUENESS and TRUENESS AIR Blood Glucose Monitoring Systems consist of the TRUENESS or TRUENESS AIR Blood Glucose Meter and the TRUENESS Blood Glucose Test Strips. The TRUENESS Blood Glucose Control Solutions (level 1 and level 2), and the TRUEdraw Lancing Device with TRUEPLUS lancets are for use with the system and are sold separately.

The TRUENESS AIR Blood Glucose Meter and TRUENESS Blood Glucose Meter differ only in Bluetooth functionality which is present only in the TRUENESS AIR Blood Glucose Meter.

B Principle of Operation:

The TRUENESS and TRUENESS AIR Blood Glucose Monitoring Systems measure the amount of glucose in whole blood quantitative using fresh capillary whole blood from the fingertip and reports the plasma equivalent glucose results. The glucose measurement is achieved by using an amperometric detection method that uses glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) based chemistry. When a drop of blood is applied to the test strip it is pulled into the test strip through capillary action. Glucose in the sample reacts with test strip chemistry generating electrons and producing a current that is proportional to the glucose concentration in the sample. After the reaction time, the detected current is calculated by the meter and the resulting glucose concentration is displayed by the meter.

C Instrument Description Information:

1. Instrument Name:

   Trueness Blood Glucose Meter
   Trueness Air 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:

   Two (2) levels of glucose control solutions are available with this system, but are sold separately. Recommendations on when to test the control materials are provided in the labeling. If control test results are out of range when comparing to the range printed on the test strip vial, the user is advised to repeat the test. If problems continue, the user is cautioned not to use the meter and to contact customer service. The control solutions are not included in the average of the patient results when the measurements are performed in control testing mode.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Contour® next GEN Blood Glucose Monitoring System

B Predicate 510(k) Number(s):

K193407

C Comparison with Predicate(s):

Device & Predicate Device(s):	K231476	K193407
Device Trade Name	TRUENESS and TRUENESS AIR Blood Glucose Monitoring Systems	Contour® next GEN Blood Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	Quantitatively measure glucose in fresh capillary whole blood	Same

Device & Predicate Device(s):	K231476	K193407
	drawn from the fingertips by people with diabetes at home as an aid in monitoring the effectiveness of a diabetes control program.	
Reagent Enzyme	FAD-Glucose Dehydrogenase	Same
Test Time	5 seconds	Same
General Device Characteristic Differences		
Measurement Range	40 – 600 mg/dL	20 – 600 mg/dL
Sample Size	1 μL	0.6 μL

VI Standards/Guidance Documents Referenced:

FDA Guidance Document: Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use. Issued on September 29, 2020.

IEC 60601-1-2:2014 Medical Electrical Equipment Part 1-2: General Requirement for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

VII Performance Characteristics (if/when applicable):

The TRUENESS AIR Blood Glucose Monitoring System was used as a representative model for the performance evaluations below to support both the TRUENESS and the TRUENESS AIR Blood Glucose Monitoring Systems because the only difference between the systems is the present of Bluetooth technology in the TRUENESS AIR Blood Glucose Meter.

A Analytical Performance:

1. Precision/Reproducibility:

Within-Run Precision (Repeatability)

Within-run precision studies were performed using venous whole blood samples of 5 glucose levels (40-50, 51-110, 111-150, 151-250, 251-400 mg/dL). Each sample was tested in replicates of ten with three test strip lots and 10 meters for a total of 300 tests per glucose level. Results are summarized below:

Venous Blood Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV
40-50	Lot 1	100	43.5	1.6	3.7%
	Lot 2	100	43.5	1.6	3.8%
	Lot 3	100	44.9	2.1	4.6%
	Combined	300	44.0	1.8	4.0%
51-110	Lot 1	100	101.2	3.2	3.1%
	Lot 2	100	103.0	3.6	3.5%
	Lot 3	100	99.9	4.0	4.0%
	Combined	300	101.4	3.5	3.5%
111-150	Lot 1	100	128.4	4.1	3.2%
	Lot 2	100	128.1	4.2	3.3%
	Lot 3	100	132.1	4.5	3.4%
	Combined	300	129.5	4.2	3.3%
151-250	Lot 1	100	211.1	7.1	3.4%
	Lot 2	100	205.7	4.9	2.4%
	Lot 3	100	208.8	6.5	3.1%
	Combined	300	208.6	6.3	3.0%
251-400	Lot 1	100	334.2	9.0	2.7%
	Lot 2	100	337.0	12.1	3.6%
	Lot 3	100	347.1	8.1	2.3%
	Combined	300	339.4	9.7	2.9%

Intermediate Precision (Between Run)

Intermediate (between run) precision was evaluated using five levels of glucose control solutions (40-50, 51-110, 111-150, 151-250, 251-400 mg/dL), 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 level. Results are summarized below:

Control Levels (mg/dL)	Strip lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
40-50	Lot 1	100	43.9	2.2	4.9%
	Lot 2	100	45.9	1.7	3.6%
	Lot 3	100	45.1	1.8	4.0%
	Combined	300	45.0	1.9	4.3%
51-110	Lot 1	100	97.9	3.1	3.2%
	Lot 2	100	98.9	2.3	2.3%
	Lot 3	100	97.8	2.1	2.2%
	Combined	300	98.2	2.5	2.6%

Control Levels (mg/dL)	Strip lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
111-150	Lot 1	100	137.6	3.7	2.7%
	Lot 2	100	138.3	3.2	2.3%
	Lot 3	100	137.5	3.0	2.2%
	Combined	300	137.8	3.3	2.4%
151-250	Lot 1	100	203.4	5.0	2.5%
	Lot 2	100	205.2	3.7	1.8%
	Lot 3	100	203.8	3.4	1.7%
	Combined	300	204.1	4.2	2.1%
251-400	Lot 1	100	384.0	10.5	2.7%
	Lot 2	100	380.7	7.5	2.0%
	Lot 3	100	380.5	9.3	2.4%
	Combined	300	381.7	9.2	2.4%

2. Linearity:

The linearity of the glucose measurement was evaluated using venous whole blood spiked with glucose. Eleven whole blood samples were adjusted to the following glucose concentrations (as measured by the ABL90 FLEX analyzer as the comparator method): 31.1, 85.9, 149.5, 208.6, 261.9, 315.6, 377.9, 444.6, 502.4, 554.4, and 614.0 mg/dL. The summary of the linear regression analysis for each lot was as follows:

Test Strip Lot #	**Slope**	**y-intercept**	**R^2 value**
Lot 1	1.0003	-3.2540	0.9994
Lot 2	1.0026	-3.1289	0.9987
Lot 3	0.9970	-3.7063	0.9991
Combined	0.9999	-3.3630	0.9990

The results of the study support the sponsor's claimed glucose measuring range of 40-600 mg/dL. If a sample result is less than 40 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 interferences, the sponsor used venous whole blood samples adjusted to 3 glucose concentration ranges: 50-70, 110-130, and 225-270 mg/dL. Each of these samples was divided into a test pool and a control pool, with each of the potential endogenous and exogenous interfering substances added to the test pool. The % difference between the test sample and the control sample was calculated using mean of 10 replicates for each of the 3

strip lots tested. The highest concentrations tested at which no significant interference was observed (within ± 10% average bias between test and control samples) are presented in the following table:

Potential Interferent	Maximum tested concentration with no significant interference (mg/dL)
Acetaminophen	20
Ascorbic acid	6
Conjugated Bilirubin	37.5
Unconjugated Bilirubin	40
Cholesterol	500
Creatinine	15
Dopamine	0.09
EDTA	0.1
Galactose	60
Gentisic acid	1.8
Reduced Glutathione	4.6
Hemoglobin	1000
Ibuprofen	50
L-Dopa	0.75
Maltose	480
Mannitol	1800
Methyldopa	2
Salicylic acid	60
Sodium	180 mmol/L
Tolbutamide	72
Tolazamide	9
Triglycerides	1500
Uric acid	23.5
Xylose	5
Icodextrin	1094.4
Pralidoxime iodide	5
Sorbitol	0.09
Xylitol	0.09
Lactitol	0.09
Isomalt	0.09
Maltitol	0.09
Heparin Lithium	300 IU/dL
Acetone	70
Caffeine	6
Ceftriaxone	81
Ethanol	400
Glipizide	0.2
Maltotetraose	70

Potential Interferent	Maximum tested concentration with no significant interference (mg/dL)
Maltotriose	180
Metformin	4
Naproxen Sodium	55
Tetracycline	1.5
Warfarin (Coumadin)	1

The sponsor has included the following in the labeling:

- Xylose: Do not perform test during or soon after xylose absorption testing. High xylose level in the blood will cause inaccurate results.

4. Assay Reportable Range:

   40 – 600 mg/dL

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

   The glucose measurement functionality of the TRUENESS Blood Glucose Monitoring System and TRUENESS AIR Blood Glucose Monitoring System are traceable to the NIST SRM 917c glucose reference material. The method comparison/lay-user study was performed using the ABL90 Flex Plus Analyzer as the comparator method (see section VII.C.3).

   Open and Closed Vial Stability

   Test strip stability was assessed using accelerated and real-time stability studies. Testing protocols and acceptance criteria were reviewed and found to be acceptable. The labeling includes claims that the TRURNESS Blood Glucose Test Strips are stable for 6 months after opening and 24 months unopened when stored between 41-86ºF (5ºC – 30ºC) and 10% - 85% relative humidity.

6. Detection Limit:

   Please see linearity section.

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.

2. Matrix Comparison:

   Not applicable. The device is only intended for use with fresh capillary whole blood.

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 TRUENESS AIR Blood Glucose Monitoring System in the hands of lay users, the sponsor performed a study with 354 lay user participants who collected and tested their own fingertip capillary blood samples. The glucose concentrations in the samples ranged from 42-460 mg/dL including 11 native samples < 80 mg/dL and 33 native samples > 250 mg/dL as measured by the laboratory comparator method, the ABL90 Flex Plus (k160153). Results were analyzed by comparing blood glucose results obtained from the TRUENESS Blood Glucose meter by the lay user against the laboratory comparator value obtained by healthcare professionals. Results are summarized in the tables below:

System Accuracy Results for Entire Glucose range				
Sample Site	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Fingertip	185 / 354 (52.3%)	291 / 354 (82.2%)	345 / 354 (97.5%)	353 / 354 (99.7%)

Regression analysis: $y = 0.987x – 1.508$ $R^2 = 0.981$

Usability:

At the end of the 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. From the sponsor's analysis of the questionnaire responses, the participants overall were satisfied with the ease of operation by following the instructions for use in the User's Manual and the overall performance of the subject blood glucose monitoring system.

Labeling Readability

The readability of the over-the counter, home use labeling was evaluated using a Flesch-Kincaid analysis and demonstrated that the readability grade level scores were less than an 8th grade level.

Extreme Glucose Study

System accuracy at extreme glucose levels was evaluated by measuring 51 samples with glucose concentrations below 80 mg/dL and 50 samples with glucose concentrations greater than 250 mg/dL on the TRUENESS AIR Blood Glucose Monitoring System using 3 lots of test strips. Results on the candidate device were compared to the results obtained using the comparator method (ABL90 FLEX Plus Analyzer). Results are summarized below:

System accuracy results for extreme low (<80mg/dL) glucose readings			
Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
28 / 51 (54.9%)	44 / 51 (86.3%)	50 / 51 (98%)	51 / 51 (100%))
System Accuracy results for extreme high (>250mg/dL) glucose readings			
Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
28 / 50 (56%)	47 / 50 (94%)	49 / 50 (98%)	50 / 50 (100%)

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The sponsor included the following expected glucose values in their labeling:

Time	Blood glucose result for people without diabetes
Before eating	< 100 mg/dL
2 hours after a meal	< 140 mg/dL

Source: American Diabetes Association Standards of Medical Care in Diabetes, January 2023 Volume 46, Supplement 1: S25.

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 15-60% (15, 20, 25, 30, 35, 42, 50, 55 and 60%) at five levels of glucose (40–50, 51–110, 111– 50, 151– 250, and 251–400 mg/dL). Each sample was tested in replicates of 10 using 10 meters and three test strip lots. Results from the candidate system were compared to results obtained using the comparator method (ABL90 FLEX analyzer) a laboratory-based comparator measurement and to the candidate system results of samples with normal hematocrit (~42%). The results demonstrated acceptable performance across the claimed hematocrit range of 15-60%.

2. Altitude Effects

To evaluate the effects of altitude on the TRUENESS AIR Blood Glucose Monitoring System results, contrived venous whole blood samples were altered to 6 glucose concentrations (45-55, 76-84, 124-136, 190-210, 338-362, and 507-548 mg/dL) and tested at 10,000 ft feet above sea level. The meter results were compared to those obtained with the comparator method (ABL90 FLEX analyzer). The results support the labeling claim that the system functions as intended at altitudes up to an altitude of 10,000 feet.

3. Sample Volume

The sponsor performed a study to support the claimed minimum sample volume of 1.0 µL for the TRUENESS and TRUENESS AIR Blood Glucose Monitoring Systems. Venous whole blood samples with three levels of glucose concentrations (approximately 55, 110, 215 mg/dL) were tested at five sample volumes (0.8, 0.9, 1.0, 1.1 and 1.2 µL) using 3 lots of the test strips and 10 meters. Values obtained with the candidate system were compared to those obtained using the comparator ABL90 FLEX method. The meter has an error message displayed, E-7, if enough blood is not added to the test strip. The results of the study support the claimed sample volume of 1.0 µL and that the insufficient sample volume error message functions as intended.

4. System Operating Conditions Testing

The sponsor performed operating condition studies using venous whole blood samples with 5 glucose levels (40-50, 51-110, 111-114, 151-250, and 280-400 mg/dL) to evaluate temperatures ranging from 50-104°F (10-40°C) and relative humidity from 10% to 90%. Candidate system results obtained at the following temperature and humidity combinations were compared to candidate system results obtained at ambient conditions (23°C/50%RH): low temperature/low humidity, low temperature/high humidity, high temperature/low humidity and high temperature/high humidity. The results support the claims in the labeling that the system can be used in conditions of 50-104°F (10-40°C) with relative humidity of 10 to 90%.

5. Flex studies

The following additional flex studies were performed with the TRUENESS AIR Blood Glucose Monitoring System: sample perturbation, intermittent sampling, used test strips, drop, and shipping testing. The testing performed demonstrated that the device is robust under these conditions.

6. Electrical Safety and EMC Testing

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

7. Infection Control Testing

The device system is intended for single-patient use only. Disinfection efficacy studies were performed on the external materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, SUPER SANI-CLOTH ® Germicidal Disposable Wipes (EPA Registration #9480-4). A robustness study was also conducted by the sponsor demonstrating that there was no change in performance or in the external materials of the meter after 520 cleaning and disinfection cycles using the SUPER SANI-CLOTH ® Germicidal Disposable Wipes. The robustness studies were designed to simulate 5 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

Glucose test strip lot release protocols 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.