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

A. 510(k) Number:

k153561

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose from the finger, palm, forearm, upper arm, calf, or thigh

D. Type of Test:

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

E. Applicant:

Andon Health Co., Ltd.

F. Proprietary and Established Names:

AG-607 Blood Glucose Monitoring System

AG-607 Multi Blood Glucose Monitoring System

G. Regulatory Information:

Regulation	Name	Class	Product Code	Panel
21 § 862.1345	Glucose test system	II	NBW	(75) Chemistry
21 § 862.1345	Glucose Dehydrogenase	II	LFR	(75) Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

AG-607 Blood Glucose Monitoring System:

The AG-607 blood glucose monitoring system is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh. The AG-607 blood glucose monitoring system is intended to be used by a Single person and should not be shared.

The AG-607 blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The AG-607 blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative Site Testing (AST) should be done only during steady-state times (when glucose levels are not changing rapidly).

The EGS-2003 test strips are for use with the AG-607 blood glucose meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh.

AG-607Multi Blood Glucose Monitoring System:

The AG-607Multi blood glucose monitoring system is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, upper arm, calf, or thigh. The AG-607Multi blood glucose monitoring system is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as and aid to monitor the effectiveness of diabetes control program. The system is only used with single-use auto-disabling lancing device.

The AG-607Multi blood glucose monitoring system should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative Site Testing (AST) should be done only during steady-state times (when glucose levels is not changing rapidly).

The EGS-2003multi test strips are for use with the AG-607Multi blood glucose meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf or thigh.

3. Special conditions for use statement(s):

Applicable to both devices:

- The blood glucose monitoring system is not intended for use on neonates
- Not to be used for the diagnosis of or screening for diabetes
- Not for use for patients in a hyperglycemic-hyperosmolar state, with or without ketosis
- Not for use on critically ill patients

- Not to be used for patients who are dehydrated, hypertensive, hypotensive, or in shock
- For in vitro diagnostic use (external use only)
- Alternative site testing (AST) should not be used to calibrate continuous glucose monitoring systems (CGMs).
- Results from alternative site testing should not be used in insulin dose calculations.
- The system cannot be used above the altitude of 10744 feet (3275 meters)

Applicable to the AG-607Multi System:

- The meter should be disinfected after use on each patient
- Only auto-disabling lancing devices may be used with this device
- The blood glucose monitoring system is not intended for use on artery blood, serum, plasma and venous blood samples
- The blood glucose monitoring system should be only used with the EGS-2003Multi test strips.

Applicable to the AG-607 System:

- Single person measurement only (it should not be shared)
- The blood glucose monitoring system should be only used with the EGS-2003 test strips

4. Special instrument requirements:

   AG-607 Blood Glucose Meter

   AG-607 Multi Blood Glucose Meter

I. Device Description:

The AG-607 Glucose Monitoring System and the AG-607Multi Glucose Monitoring System each consist of a blood glucose meter, single use test strips (EGS-2003 and EGS-2003Multi), sterile lancets, lancing device and the control solutions. The Andon Glucose Control Solutions Level I, Level II, and Level III were previously cleared (k110017).

J. Substantial Equivalence Information:

1. Predicate device name(s):
   AG-608N Single Blood Glucose Monitoring System

2. Predicate 510(k) number(s):
   K110017

3. Comparison with predicate:

Similarities		
Item	Candidate Device AG-607 Blood Glucose Monitoring System	Predicate Device AG-608N Single Blood Glucose Monitoring System
Indications for Use	Intended for the quantitative measurement of glucose in fresh capillary blood samples by people with diabetes at home to monitor the effectiveness of diabetes control	Same
Test Principle	Amperometry	Same
Hematocrit Range	20-60%	Same
Measuring Range	20-600 mg/dL	Same
Sample Volume	0.7 μL	Same
Test Time	5 seconds	Same
Coding	Manual code entry	Same
Control Solutions	AGS1000I Control Solutions (Level I, Level II and Level III)	Same
Altitude	10744 ft	Same
Operating Temperature Range	10-40ºC	Same
Alternative Site Testing	Palm, forearm, upper arm, calf, or thigh	Same

Differences		
Item	Candidate Device AG-607 Blood Glucose Monitoring System	Predicate Device AG-608N Single Blood Glucose Monitoring System
Dimensions	110mm x 52mm x 20.5mm	87mm x 53mm x 9.9mm
Qualified Test Strip (Chemistry)	EGS-2003 Test Strip (GDH-FAD)	AGS-1000N Test Strip (Glucose Oxidase)
Power Source	DC 3.0V (2xLR03) batteries	DC 3.0V (CR2032) battery
Battery Life	1000 tests	500 tests
PC Connection	N/A	USB

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

IEC 60601-1-2:2007 Medical electrical equipment, Part 1: General requirements for basic safety

and essential performance, collateral standard: electromagnetic compatibility

L. Test Principle:

The AG-607 Blood Glucose Monitoring System measures glucose amperometrically. The system is designed as an amperometric measurement device using current generated from the redox reaction as the measurable response.

The EGS-2003 test strip employs flavin adenine dinucleotide glucose dehydrogenase (FAD-GDH) enzyme chemistry as the dry reagent assay for glucose in whole blood. This enzyme assay, with a redox chemical "mediator" reaction, is used to generate an electrical current proportional to the glucose concentration in the blood sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

These two systems are identical except for the intended use. Therefore there is only one set of performance data presented here, which is representative of the performance of both systems.

a. Precision/Reproducibility:

Repeatability studies were performed with venous whole blood samples at five glucose concentration ranges using three test strip lots and ten AG-607 blood glucose meters. Ten runs were performed on each sample with four replicates run on strip lots #1 and #2, and two replicates run on strip lot #3, resulting in a total of 40, 40, and 20 replicates for each test strip lot, respectively, at each glucose level. Results are summarized below:

Glucose Level	30-50 (mg/dL)	50-110 (mg/dL)	110-150 (mg/dL)	150-250 (mg/dL)	250-400 (mg/dL)
Mean (mg/dL)	43.8	77.6	144.6	230.4	343.8
SD (mg/dL)	2.4	3.6	5.0	7.6	11.6
CV (%)	5.6	4.6	3.5	3.3	3.4
N	100	100	100	100	100

Intermediate precision was evaluated using three glucose control solutions, Level I, Level II, and Level III using three test strip lots and 10 AG-607 blood glucose meters. One run was performed on each of ten days with each glucose control solution, with three replicates for strip lots #1 and #2, and four replicates for strip lot #3. Results are summarized below:

Glucose Control Solution	Level I	Level II	Level III
Mean (mg/dL)	58.1	86.8	310.2
SD (mg/dL)	2.0	2.5	8.5
CV%	3.5	2.9	2.7
N	100	100	100

b. *Linearity/assay reportable range:*
Linearity was evaluated using ten venous blood glucose samples with glucose concentrations ranging from 19.7 to 600.0 mg/dL (19.7, 32.5, 73.6, 126.5, 194.9, 279.8, 367.0, 457.5, 538.5, 600.0 mg/dL) as assessed by the reference method (YSI 2300). Each sample was measured five times using the AG-607 meter, and then measured using a laboratory based reference method (YSI 2300). The results from regression analysis are summarized below:

$y = 0.988x + 1.518$; $R^2 = 0.9995$

The meter will display "LO" when the result is less than 20 mg/dL and "HI" when result is greater than 600 mg/dL. The sponsor validated the "LO" and "HI" functions and demonstrated that they functioned as intended.

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

The system is traceable to NIST SRM #917c reference material and calibrated to be plasma-equivalent.

Control Solution Value Assignment and Stability:
The Andon Glucose Control Solutions Level I, Level II, and Level III were previously cleared (k110017). Control solutions are stable for 24 months when stored at 39 to 86ºF (4-30ºC) with relative humidity of <80% with a 90 day stability after opening when stored at 39 to 86ºF.

Test Strip Stability:
Test strip stability was assessed with accelerated studies and on-going real-time studies. The testing protocols and acceptance criteria were reviewed and found to be acceptable. The manufacture
claims shelf life stability of 24 months when stored at 39 to 86 ºF (4-30 ºC) with relative humidity of 10-85% and a 5 month stability after opening when stored at 39-86 ºF with relative humidity of 10-85%.

d. Detection limit:

The measuring range of the AG-607 Blood Glucose Monitoring System is 20-600 mg/dL supported by the linearity assay study above (M.1.b).

e. Analytical specificity:

Interference studies were performed with spiked venous blood samples at two glucose concentrations (80 and 350 mg/dL) that were prepared and divided into a test (spiked) pool and a control pool. The potential interferants (2 levels) were added to the sample and each sample was tested 5 times, and the % difference between the individual measurements on the meter and the reference method (YSI 2300) results calculated. The table below lists all substances tested at concentrations with insignificant (<10%) interference.

Potential Interfering Substance	**Concentration at which no significant interference is observed (mg/dL)**
Acetaminophen	5
Ascorbic Acid	4
Bilirubin	40
Uric acid	10
Triglycerides	2000
Cholesterol	700
Hemoglobin	450
Ibuprofen	50
L-dopa	1.35
Methyldopa	1.5
Dopamine	0.09
Salicylate	60
Tolbutamide	65
Tolazamide	30
Maltose	200
Galactose	15
Icodextrin	7.5
Creatinine	5
Pralidoxime Iodide	56
Gentisic Acid	117
Glutathione	28

Based on the results of their testing the sponsor listed the following limitations in the Owner's Manual and the test strip inserts:

- Do not use during or soon after xylose absorption testing

- If you are taking acetaminophen containing drugs (Tylenol and other medicines containing acetaminophen, blood concentrations >5 mg/dL) or Vitamin C (ascorbic acid, blood concentrations >4 mg/dL) at doses higher than recommended, these may interfere with your glucose meter and cause you to get inaccurate results with this system.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison:

To assess system accuracy, results from the AG-607 Blood Glucose Monitoring System were compared to a reference method (YSI 2300). Capillary fingerstick and AST site samples were obtained by professional users from 100 participants with glucose concentrations between 41-555 mg/dL, followed by venous sample collection for reference measurement. No blood samples were altered for this test. Results of the tests from each participant are shown below:

System Accuracy for glucose concentration < 75 mg/dL

Trained Operator	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Finger	3/6 (50%)	6/6 (100%)	6/6 (100%)
Palm	4/7 (57%)	6/7 (86%)	7/7 (100%)
Forearm	3/7 (43%)	5/7 (71%)	7/7 (100%)
Upper arm	5/8 (63%)	7/8 (88%)	8/8 (100%)
Calf	3/7 (43%)	7/7 (100%)	7/7 (100%)
Thigh	6/9 (67%)	8/9 (93%)	9/9 (100%)

System Accuracy for glucose concentration ≥ 75 mg/dL

Trained Operator	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Finger	60/94 (64%)	85/94 (90%)	94/94 (100%)	94/94 (100%)
Palm	58/93 (62%)	82/93 (88%)	93/93 (100%)	93/93 (100%)
Forearm	62/93 (67%)	86/93 (92%)	93/93 (100%)	93/93 (100%)
Upper arm	52/92 (57%)	83/92 (90%)	92/92 (100%)	92/92 (100%)
Calf	53/93 (57%)	78/93 (84%)	93/93 (100%)	93/93 (100%)
Thigh	59/91 (65%)	85/91 (93%)	91/91 (100%)	91/91 (100%)

Linear Regression Analysis

Trained Operator	Slope	Intercept	R^2	No. Reps
Finger	1.014	-2.355	0.9849	100
Palm	1.005	-2.101	0.9831	100
Forearm	1.001	-2.040	0.9855	100
Upper Arm	1.001	-1.585	0.9843	100
Calf	1.008	-2.506	0.9842	100
Thigh	0.995	-0.613	0.9432	100

b. Matrix comparison:

Not applicable. Fresh capillary whole blood is the only acceptable 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):

User Performance Study

To assess the performance of the AG-607 Blood Glucose Monitoring System in the hands of lay users, the sponsor performed a study with 350 lay user participants who collected and tested their own samples. Results were analyzed by comparing capillary whole blood glucose results obtained by the lay users with the AG-607 Blood Glucose Monitoring System against results obtained with the same fingerstick blood samples from the same patients analyzed by laboratory reference method (YSI 2300). The glucose concentrations in the samples ranged from 40-538 mg/dL as measured by the laboratory reference method. Results are summarized in the tables below:

System Accuracy for glucose concentration < 75 mg/dL

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Finger	31/55 (56.4%)	51/55 (91.1%)	55/55 (100%)
Palm	32/56 (57.1%)	55/56 (98.2%)	56/56 (100%)
Forearm	31/55 (56.3%)	54/55 (98.2%)	55/55 (100%)
Upper arm	33/55 (60%)	53/55 (96.4%)	55/55 (100%)

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Calf	29/53 (54.7%)	50/53 (94.3%)	53/53 (100%)
Thigh	32/55 (58.2%)	53/55 (96.4%)	55/55 (100%)

System Accuracy for glucose concentration ≥ 75 mg/dL

	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Finger	124/295 (42%)	242/295 (82%)	292/295 (99%)	295/295 (100%)
Palm	122/294 (41.5%)	232/294 (78.9%)	286/294 (97.3%)	294/294 (100%)
Forearm	136/295 (46.1%)	235/295 (79.7%)	285/295 (96.6%)	295/295 (100%)
Upper arm	134/295 (45.4%)	237/295 (80.3%)	287/295 (97.3%)	295/295 (100%)
Calf	122/297 (41.1%)	245/297 (82.5%)	288/297 (97%)	297/297 (100%)
Thigh	136/295 (46.1%)	246/295 (83.4%)	286/295 (96.3%)	295/295 (100%)

Regression analysis of results from lay users:

	Finger	Palm	Forearm	Upper arm	Calf	Thigh
Slope	0.9838	0.9964	0.9809	0.9853	0.9856	0.9955
Y-Intercept	-1.00	-2.29	-0.64	-0.78	-0.57	-1.54
R^2	0.9813	0.9829	0.9844	0.9812	0.9850	0.9842

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   The sponsor included the following expected values for people without diabetes in the labeling:
   Fasting and before meals: <100 mg/dL
   2 hours after meals: <140 mg/dL

   Source: American Diabetes Association: Diagnosis and Classification of Diabetes

Mellitus (Position Statement). Diabetes Care 36 (Supp.1) S15, 2016.

N. Instrument Name:

AG-607 Blood Glucose Monitoring System

AG-607Multi 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. Minimal sample volume is 0.7 µL per test.

   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 _____

   The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

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 glucose test is intended to be used with capillary whole blood from the finger, palm, forearm, upper arm, calf, or thigh only. The sample is applied directly to the test strip and testing is performed immediately. Sample storage is not required.

5. Calibration:

   Calibration of the meter occurs by manual entry of a calibration code that is included with each vial of test strips.

6. Quality Control:

   Three levels of aqueous glucose control solutions are available with this system (level I, level II, level III) but must be purchased separately. The user must manually enter a Control Solution testing mode when testing control solutions. Controls are not included in patient glucose averaging when tested using Control Solution testing mode. Recommendations on when to test the control materials and troubleshooting steps if the controls are outside of specifications are provided in the labeling. An acceptable range for each control level is printed on the test strip vial label.

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 AG-607 Blood Glucose Monitoring System using the EGS-2000 test strips, venous blood samples with hematocrit levels of 20, 30, 42, 50, and 60% were tested at 3 glucose concentrations (50, 120, and 350 mg/dL). The evaluation included 5 meters, each tested with two replicates using 3 lots of test strips. Results from the meter were compared to results obtained using a laboratory-based reference method (YSI 2300). The evaluation of percent bias relative to YSI demonstrated acceptable performance across the claimed hematocrit range of 20-60%.

2. Altitude study:
   To evaluate the effect of altitude on the AG-607 Blood Glucose Monitoring System, meters were tested at two altitudes above sea level (0 ft and 10,744 ft). Venous whole blood samples were obtained from 20 volunteers (glucose range 64-334 mg/dL). Results were compared to results obtained using a laboratory-based reference method (YSI 2300) and demonstrated that altitudes up to 10,744 feet above sea level have no significant effect on blood glucose measurements from the AG-607 Blood Glucose Monitoring System.

3. Sample Volume Study:
   To demonstrate the minimum sample volume, 0.5, 0.6, 0.7, 1.0, and 2.0 µL samples of venous whole blood at glucose concentrations of 47, 65, 109, 156, 231, 371, and 455 mg/dL were tested. Values obtained were compared to values obtained using a laboratory-based reference method (YSI 2300). Results support minimum sample volume of 0.7 µL.

4. Infection Control Study:
   As established in k110017. The AG-607 Blood Glucose Meter uses the same case materials as the predicate device. Disinfection efficacy studies were performed on the

materials comprising the meters and lancing device by outside commercial testing demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, CaviWipes (EPA Registration #46781-8). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials for each of the meters and lancing device after 11,000 cleanings and 11,000 disinfection steps with the CaviWipes. The robustness studies were designed to stimulate 3 years of multiple-patient use and 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

5. Environmental testing for temperature and relative humidity:
   Temperature and humidity operating conditions were evaluated for temperatures ranging from 50°F to 104°F (10°C to 40°C) and relative humidity between 25 and 80% R.H. using 3 glucose concentration levels of venous whole blood (75, 120, and 290 mg/dL). Individual glucose measurements were compared to the reference method (YSI) and percent bias were calculated. Results demonstrated that glucose measurements on the AG-607 Glucose Monitoring System were not affected at temperatures ranging from 50°F to 104°F (10°C to 40°C) and relative humidity between 25 to 80% R.H. If the operating temperature is outside of these conditions, the meter displays an error message instead of a blood glucose value.

6. EMC and electrical safety:
   The sponsor provided appropriate documentation certifying that electromagnetic (EMC) testing was performed and the device systems were found to be compliant.

7. Readability study: A readability evaluation was conducted which determined that the reading grade level is at the 8^{th} grade level or less.

8. This device was cleared after the FDA issued final guidance documents for prescription use blood glucose monitoring systems (BGMS) and over-the-counter use blood glucose monitoring systems (SMBG). However, the recommendations in the guidance documents were not followed for this device since the submission was received prior to the finalization of the guidance documents.

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.