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

A. 510(k) Number:

k101307

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, electrochemical biosensor, glucose oxidase

E. Applicant:

Andon Medical Co., Ltd.

F. Proprietary and Established Names:

AG-6081 Single Blood Glucose Monitoring System

AG-6951 Single Blood Glucose Monitoring System

AG-6081 Multi Blood Glucose Monitoring System

AG-6951 Multi Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

   21 CFR § 862.1345, Glucose Test System

   21 CFR 862.1660, Quality Control Material (assayed and unassayed)

2. Classification:

Class II, Class I (reserved)

3. Product code:

   NBW, System, Test, Blood Glucose, Over The Counter.

   CGA, Glucose Oxidase, Glucose

   JJX, Quality Control Material (Assayed and Unassayed)

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indications for Use below.

2. Indication(s) for use:

   The **AG-6081 single 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 and thigh. The AG-6081 Single Blood Glucose Monitoring System is to be used by a single person and should not be shared.

   The AG-6081 Single 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-6081 Single Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady state times (when glucose is not changing rapidly).

   The AGS-1100 single Blood Glucose Test Strips are for use with the AG-6081 Single Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

   The AGS-1100 Controls are intended for *in vitro* diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the AG-6081 Single Blood Glucose Monitoring System and the AG-6081 Single Blood Glucose Test Strips.

   The **AG-6951 single 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 and thigh. The AG-6081 Single Blood

Glucose Monitoring System is to be used by a single person and should not be shared.

The AG-6951 Single 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-6951 Single Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady state times (when glucose is not changing rapidly).

The AGS-1100 Single Blood Glucose Test Strips are for use with the AG-6951 Single Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The AGS-1100 Controls are intended for *in vitro* diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the AG-6951 Single Blood Glucose Monitoring System and the AG-6951 Single Blood Glucose Test Strips.

This system contains a speaking function that provides audible test results for users with impaired vision. The audible function does not provide complete instructions for all functions of the meter or for performing a glucose test.

The **AG-6081 MULTI 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 and thigh. The AG-6081 MULTI 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 an aid to monitor the effectiveness of a diabetes control program.

The AG-6081MULTI Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing such as the palm, forearm, upper arm, calf and thigh should be done only during steady-state times (when glucose is not changing rapidly).

The AGS-1100 MULTI Blood Glucose Test Strips are for use with the AG-6081 MULTI Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The AGS-1100 Controls are intended for *in vitro* diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the AG-6081 MULTI Blood Glucose Monitoring System and the AG-6081 MULTI Blood Glucose Test Strips.

The **AG-6951 MULTI 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 and thigh. The AG-6081 MULTI 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 an aid to monitor the effectiveness of a diabetes control program.

The AG-6951MULTI Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing such as the palm, forearm, upper arm, calf and thigh should be done only during steady-state times (when glucose is not changing rapidly).

The AGS-1100 MULTI Blood Glucose Test Strips are for use with the AG-6951 MULTI Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, upper arm, calf and thigh.

The AGS-1100 Controls are intended for *in vitro* diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the AG-6951 MULTI Blood Glucose Monitoring System and the AG-6951 MULTI Blood Glucose Test Strips.

3. Special conditions for use statement(s):

- For in vitro diagnostic use only
- For Professional and Over the Counter Use
- Not intended for use on neonates
- Not for diagnosis of or screening for diabetes mellitus
- Not to be used for patients who are dehydrated, hypotensive, in shock, critically ill or in a hyperosmolar state
- Allows alternative site testing
- Multiple-patient use devices (AG-6081- multi and AG-6951-multi) must be disinfected between used following labeling recommendations
- Multiple patient use systems should only use single use, auto disabling lancing devices.
- Single-patient use devices (AG-6081 and AG-6951) are for single-patients only and should not be shared.

4. Special instrument requirements:

The AG-6081 Single and AG-6095 Single meters

The AG-6081 MULTI and AG-6095 MULTI meters

Disposable, single use lancing devices are used with the AG-6081 MULTI and AG-6095 MULTI blood Glucose Monitoring Systems.

I. Device Description:

The AG-6081 Single and AG-6951 Single Blood Glucose Monitoring Systems contain a

blood glucose meter (AG-6081 Single or AG-6951 Single, respectively) AGS-1100 Single blood glucose test strips. These are no code meters. The Level ll control solution, Owner's booklet and carrying case are provided in the kit. Level I and Level III control solutions, lancing device, and sterile lancets are sold separately.

The AG-6081 MULTI and AG-6951 MULTI Blood Glucose Monitoring Systems contain a blood glucose meter (AG-6081 MULTI or AG-6951 MULTI, respectively) AGS-1100 MULTI blood glucose test strips. These are no code meters. Level II control solution, Owner's booklet and carrying case are provided in the kit. Level I and Level III control solutions, and auto-disabling lancing devices are sold separately.

The differences between the single-patient use (AG-6081 Single and the AG-6951 Single) and the multiple patient use systems (AG-6081 MULTI and AG-6951 MULTI) are the labeling, which includes the names of the system components, disinfection instructions for using the device on single-patients versus multiple patient use settings, and the lancing devices that can be used with the different systems.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   AG-606 Blood Glucose Monitoring System

2. Predicate 510(k) number(s):
   k073030

3. Comparison with predicate:

Similarities and Differences			
Item	Device AG-6081 Single Blood Glucose Monitoring System	Device AG-6081 MULTI Blood Glucose Monitoring System	Predicate AG-606 Blood Glucose Monitoring System (k073030)
Intended Use/Indications for Use	It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program.	It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program.	Same
Type of Meter	Biosensor (Electrode)	Biosensor (Electrode)	Same
Detection Method	Amperometry	Amperometry	Same
Enzyme	Glucose Oxidase	Glucose Oxidase	Same

Sample Application	Blood sample is placed directly on the test strip after finger is lanced	Blood sample is placed directly on the test strip after finger is lanced	Same
Sample Type	Fingerstick and Alternative Site Testing (AST) capillary whole blood	Fingerstick and Alternative Site Testing (AST) capillary whole blood	Capillary Whole Blood
Measurement Range	20-600mg/dL	20-600mg/dL	Same
Hematocrit Range	20-60%	20-60%	30-55%
Dimensions	87 mm x53 mm x 9.9 mm	87 mm x53 mm x 9.9 mm	82 mm x 59 mm x 20mm
Memory Feature	500 measurement results with date and time display	500 measurement results with date and time display	350 measurement results with date and time display
Qualified Test Strip	AGS-1100 Single Blood Glucose Test Strips	AGS-1100 MULTI Blood Glucose Test Strips	AGS-600 Test Strip
Sample Volume	Minimum 0.7 µ1	Minimum 0.7 µ1	Minimum 1 µl
Other functions	USB function present	USB function present	No USB function

Similarities and Differences			
Item	Device AG-6951 Single Blood Glucose Monitoring System	Device AG-6951 MULTI Blood Glucose Monitoring System	Predicate AG-606 Blood Glucose monitoring System (k073030)
Intended Use/Indications for Use	It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program.	It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program.	Same
Type of Meter	Biosensor (Electrode)	Biosensor (Electrode)	Same
Detection Method	Amperometry	Amperometry	Same
Enzyme	Glucose Oxidase	Glucose Oxidase	Same
Sample	Blood sample is	Blood sample is placed	Same

Similarities and Differences			
Item	Device AG-6951 Single Blood Glucose Monitoring System	Device AG-6951 MULTI Blood Glucose Monitoring System	Predicate AG-606 Blood Glucose monitoring System (k073030)
Application	placed directly on the test strip after finger is lanced	directly on the test strip after finger is lanced	
Sample Type	Fingerstick and Alternative Site Testing (AST) capillary whole blood	Fingerstick and Alternative Site Testing (AST) capillary whole blood	Capillary Whole Blood
Measurement Range	20-600mg/dL	20-600mg/dL	Same
Hematocrit Range	20-60%	20-60%	30-55%
Dimensions	52 mm x 92 mm x 21mm	52 mm x 92 mm x 21mm	82 mm x 59 mm x 20mm
Memory Feature	500 measurement results with date and time display	500 measurement results with date and time display	350 measurement results with date and time display
Qualified Test Strip	AGS-1100 Single Blood Glucose Test Strips	AGS-1100 MULTI Blood Glucose Test Strips	AGS-600 Test Strip
Sample Volume	Minimum 0.7 µ1	Minimum 0.7 µ1	Minimum 1 µl
Other functions	Voice function, USB function	Voice function, USB function	No voice or USB function present

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:

The test is based on electrochemical biosensor technology and the principle of capillary action. The electrical current generated by the reaction of glucose with the reagent of the strip is measured by the meter and is displayed as the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

M. Performance Characteristics (if/when applicable):

The AG-6081 Single and AG-6081 MULTI are the same meters and the AG-6095 Single and AG-6095 MULTI are the same meters. All four meters use the same test strip; however they have different names due to their different indications for use.

1. Analytical performance:

a. Precision/Reproducibility:

AG-6081 Single and MULTI Blood Glucose Monitoring System

Within-day precision was performed using venous whole blood samples spiked with five different glucose concentrations, three different reagent test strip lots, and 10 different AG-6081 meters. Each level was evaluated 10 times for a total of 100 tests per each glucose level. Day-to-day precision was evaluated using three glucose control solutions with concentration levels, low (45 mg/dL), normal (120 mg/dL) and high (320 mg/dL). The day-to-day precision was evaluated over a ten-day period using three different test strip lots and 10 different AG-6081 meters. A summary of the test results is presented below.

Within-day precision (whole blood)

Concentration (mg/dL) of glucose	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	100	42.1	2.7	6.37
51-110	100	96.1	3.2	3.30
111-150	100	126.4	3.7	2.96
151-250	100	208.2	6.6	3.19
251-400	100	353.5	10.5	2.98

Day-to-day precision (control materials)

Sample level (mg/dL)	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Low (45 mg/dL)	100	45.6	2.4	5.18
Normal (120 mg/dL)	100	125.8	3.9	3.13
High (320 mg/dL)	100	313.9	8.6	2.75

AG-6951 Single and MULTI Blood Glucose Monitoring System

Testing was done using whole blood heparinized samples spiked with five different glucose concentrations, three different test strip lots, and 10 different AG-6951 blood glucose meters. Each level was evaluated 10 times for a total of 100 measurements per each glucose level. Day-to-day precision was evaluated using three glucose control solutions with concentration levels, low (45 mg/dL), normal (120 mg/dL) and high (320 mg/dL). The day-to-day precision was evaluated over a ten-day period using three different test strip lots and 10 different AG-6951 meters. A summary of

the test results is presented below.

Within-day precision (whole blood)

Concentration (mg/dL) of glucose	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	100	43.1	3.0	6.87
51-110	100	96.6	3.4	3.52
111-150	100	126.9	3.9	3.09
151-250	100	209.8	7.0	3.32
251-400	100	356.8	11.0	3.08

Day-to-day precision (control materials)

Sample level (mg/dL)	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Low (45mg/dL)	100	41.8	2.0	4.68
Normal (120 mg/dL)	100	115.5	4.6	3.96
High (320 mg/dL)	100	325.4	10.3	3.17

b. Linearity/assay reportable range:

AG-6081 Single and MULTI Blood Glucose Monitoring System

Linearity testing was evaluated using 11 spiked whole blood heparinized samples over the range of 20-600 mg/dL (20, 38, 93, 146, 220, 264, 333, 396, 512, 570 and 600 mg/dL) as measured by the YSI. Measurements were taken 5 times for each level and the values of the AG-6081 meter were compared to those obtained from the YSI-2300. A regression analysis showed linearity of AG-6081 blood glucose monitoring system with a linear regression of $y=0.9957x+ 1.0031$ and an $r^2 = 0.9995$.

The claimed measuring range for this device is 20-600 mg/dL

AG-6951 Single and MULTI Blood Glucose Monitoring System

Linearity testing was evaluated using 11 spiked whole blood heparinized samples over the range of 20-600 mg/dL (20, 35, 98, 161, 223, 274, 351, 423, 504, 572, and 600 mg/dL) as measured by the YSI. Measurements were taken 5 times for each level and the values of the AG-6951 meter were compared with the values generated from YSI-2300. A regression analysis showed linearity of AG-6081 blood glucose monitoring system with a linear regression of $y=0.9893x+4.6104$ and an $r^2 = 0.9985$.

The claimed measuring range for this device is 20-600 mg/dL

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

AG-6081 and AG-6951 Blood Glucose Monitoring System

The sponsor claims that the system accuracy of the AG-6081 and AG-6951 meters is calibrated to a laboratory analyzer, YSI 2300. A method comparison was performed using the YSI 2300 as the comparative method. See comparison studies in 2a below.

Three levels of control material, Level I (60-90 mg/dL), Level II (99-149 mg/dL) and Level III (253-379 mg/dL) are available for use with the AG-6081 BGMS. Three levels of control material, Level I (58 – 88 mg/dL), level II (98 – 148 mg/dL) and Level III (262-394) are available for use with the AG-6951 BGMS. These control solutions are purchased from a commercial vendor (previously cleared under k012430). The sponsor claimed the following for stability: The shelf-life of the AG-1100 control is 24 months when stored between 36-86˚F (2-30˚C) and kept away from direct sunlight and heat. Stability is 90 days when opened and stored at 36-86˚F (2-30˚C).

Value assignment was performed by testing each level of control solution 100 times using 10 meters (5- AG-6081 and 5 -AG-6951 meters).

c. Detection limit:

AG-6081 and AG-6951 Blood Glucose Monitoring System

The measuring range of the system is 20-600 mg/dL. This range was verified by the linearity study above (section M.1.b)

d. Analytical specificity:

AG-6081 and AG-6951 Blood Glucose Monitoring System

Whole blood samples were spiked to nominal glucose concentrations of 80, 120 and 350 mg/dL. Each spiked sample was then divided into a test pool and a control pool. Each potential interfering substance was added to the test pool. Each level was analyzed for a total of 5 times with two AG-6081 meters and a total of five times using two AG-6951 meters. Three lots of AG-1100 test strips were used. The difference between the control sample and the sample containing the interfering substance were calculated. The sponsor defines no significant interference as ≤10% difference.

Exogenous Substances	Concentration showing no interference (mg/dL)
Acetaminophen	5
Ascorbic Acid	2

Ibuprofen	50
L-Dopa	.45
Methyl Dopa	0.75
Dopamine	0.03
Salicylate	60
Tolbutamide	24

Endogenous Substance	Concentration tested up to (mg/dL)
Bilirubin	15
Triglyceride	2000
Uric Acid	10

The sponsor has the following limitations in their labeling: "Metabolites: Ascorbic Acid and bilirubin at normal blood concentration does not significantly affect glucose readings. High concentrations of acetaminophen, dopamine, L-dopa, methyldopa, tolbutamide and uric acid may cause inaccurate test results. Blood glucose readings should be interpreted with caution. Lipemic Effects: Elevated blood triglycerides up to 2000 mg/dL do not significantly affect the results."

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

AG-6081 Single and AG-6081 MULTI Blood Glucose Monitoring System

The sponsor performed accuracy studies to demonstrate that the AG-6081 meter is equivalent to the YSI 2300 reference method. Capillary samples from 100 volunteers with glucose concentrations distributed over the range of 25.5 – 526 mg/dL were evaluated at two different hospitals (n=100). Each blood sample from the volunteers was divided into two, one was tested by YSI-2300 and the other was tested by the AG-6081 blood glucose monitoring system. Percent distribution of the samples corresponding to the glucose concentration ranged as follows: <50 mg/dL-9%; 51-80 mg/dL- 14%; 81-20 mg/dL- 18%; 121- 200 mg/dL – 26%; 201-300 mg/dL – 16.5%; 301-400 mg/dL – 8.5% ; and >400mg/dL – 8%. To obtain the blood glucose concentrations < 50 mg/dL and >500 mg/dL, samples were allowed to glycolyze or were spiked to achieve desired glucose concentrations. The results relative to YSI are summarized in the tables below.

System accuracy results for glucose concentrations <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
14/20 (70%)	18/20 (90%)	19/20 (98%)

System accuracy results for glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ± 20%
39/80 (49%)	64/80 (80%)	78/80 (98%)	79/80 (99%)

Regression Analysis vs. YSI

	N	Slope and y-intercept	R^2
AG-6081 vs. YSI	100	Y=0.994x+0.9242	0.9849

AG-6951 Single and AG-6951 MULTI Blood Glucose Monitoring System

The sponsor performed accuracy studies to demonstrate that the AG-6951 meter is equivalent to the YSI 2300 reference method. Capillary samples from 100 volunteers with glucose concentrations distributed over the range of 25.7 – 526 mg/dL were evaluated at two different hospitals (n=100). Each blood sample from the volunteers was divided into two, one was tested by YSI-2300 and the other was tested by AG 6951 blood glucose monitoring system. Percent distribution of the samples corresponding to the glucose concentration ranged as follows: <50 mg/dL-7.5%; 51-80 mg/dL- 14.5%; 81-20 mg/dL- 18%; 121- 200 mg/dL – 28.5%; 201-300 mg/dL – 14.5%; 301-400 mg/dL – 9.5% ; and >400mg/dL – 7.5%. To obtain the blood glucose concentrations for < 50 mg/dL and <500 mg/dL, samples were allowed to glycolyze or were spiked to achieve desired glucose concentrations. The results relative to YSI are summarized in the table below. System accuracy results for glucose concentrations <75 mg/dL

Results for glucose concentrations <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
17/19 (89%)	19/19 (100%)	19/19 (100%)

Results for glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ± 15%	Within ± 20%
53/81 (65%)	69/81 (85%)	79/81 (97%)	81/81 (100%)

Regression Analysis vs.YSI

	N	Slope and y-intercept	R^2
AG-6951 vs. YSI	100	Y= 1.015x-0.245	0.9901

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):

AG-6081 Single and MULTI Blood Glucose Monitoring System

A user performance evaluation was performed to compare the lay user self-test results with (fingertip samples) and the healthcare professional (HCP) results (with fingertip samples from professional user) with the YSI method. Studies were performed in three clinical sites with 100 lay user participants. Participants ranged from 18 – 54 years old, including 54% male and 46% female. The range of glucose values for the fingerstick samples was 53- 347 mg/dL. Linear regressions analysis results are summarized below:

Regressions between lay user's fingerstick results, HCP collected fingerstick results and the YSI method:

Tester	N	Slope and y-intercept	R^2
Lay user vs. YSI	100	y=1.0080x-1.9470	0.9877
HCP vs. YSI	100	y=1.0103x-2.8553	0.9897
Lay user vs. HCP	100	y=1.000x-0.059	0.9996

Lay user vs. YSI:

Results for glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
5/8 (62.5%)	8/8 (100%)	8/8 (100%)

Results for glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
43/92 (47%)	71/92 (77%)	91/92 (99%)	92/92 (100%)

HCP vs. YSI:

Results for glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ± 10mg/dL	Within ± 15 mg/dL
6/8 (75%)	8/8 (100%)	8/8 (100%)

Results for glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ± 20%
47/92 (51%)	74/92 (80%)	91/92 (99%)	91/92 (99%)

AG-6951 Blood Glucose Monitoring System

A user performance evaluation was performed to compare the lay user self-test results with (fingertip samples) and the healthcare professional (HCP) results (with fingertip samples from professional user) with the YSI method. Studies were performed in three clinical sites with 100 lay user participants. Participants ranged from 18 – 51 years old, including 54% male and 46% female. The range of glucose values for the fingerstick samples was 58- 361 mg/dL. Linear regressions analysis results are summarized below:

Regressions between lay user's fingerstick results, HCP collected fingerstick results and the YSI method:

Tester	N	Slope and y-intercept	R^2
Lay user vs. YSI	100	y=0.9737+4.2249	0.9765
HCP vs. YSI	100	y=0.9702+4.1765	0.9775
Lay user vs. HCP	100	y=0.9758+4.1814	0.9445

Layuser vs. YSI:

Results for glucose concentrations <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
2/5 (40%)	5/5 (100%)	5/5 (100%)

Results for glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ± 15%	Within ± 20%
49/95 (52%)	80/95 (84%)	92/95 (97%)	95/95 (100%)

HCP vs. YSI:

Results for glucose concentrations <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
4/5 (80%)	5/5 (100%)	5/5 (100%)

Results for glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ± 15%	Within ± 20%
56/95 (60%)	81/95 (85%)	94/95 (99%)	95/95 (100%)

Speaking function of the AG-6951 Blood Glucose Monitoring System

A study was conducted to evaluate the use of the speaking function on the AG-6951 Blood Glucose monitoring system by visually impaired users. The study consisted of 100 lay users (51% moderately visually impaired, 37% severely visually impaired,

and 12% profound visual impairment) and a health care professional at one hospital. The users collected their blood sample following the instructions given by the speaker function of the meter. A sample was then taken from each participant by the health care professional and measured by YSI-2300. The samples ranged from 54- 324 mg/dL.

Labeling states that this system contains a speaking function that provides audible test results for users with impaired vision and the audible function does not provide complete instructions for all functions of the meter or for performing a glucose test.

The results are summarized in the tables below:

Tester	Slope and y-intercept	R^2
Lay user vs. YSI	y=0.972x + 4.3716	0.9664
HCP vs. YSI	y=1.0072x+1.18	0.9694
Lay user vs. HCP	y=0.9373x+6.9576	0.9404

Results for glucose concentrations <75 mg/dL (layperson)

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
12/16 (75%)	14/16 (88%)	16/16 (100%)

Results for glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ± 15%	Within ± 20%
39/84 (46%)	64/84 (76%)	80/84 (95%)	84/84 (100%)

Results for glucose concentrations <75 mg/dL (professional)

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
11/16 (69%)	16/16 (100%)	16/16 (100%)

Results for glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ± 15%	Within ± 20%
42/84 (50%)	67/84 (80%)	83/84 (99%)	84/84 (100%)

AG-6081 Blood Glucose Monitoring System

Alternative testing sites: palm, forearm, upper arm, calf and thigh testing were performed using 100 patient volunteers, two AG-6081 meters and 3 lots of AGS 1100 test strips. Alternative site testing was performed by the lay user and glucose levels were collected during times of steady state conditions. The range of glucose values for these samples was 54-398 (by the finger). The linear regressions were as follows :

	Finger	Palm	Forearm	Upper Arm	Calf	Thigh
Slope (comparison	0.9836	0.9732	0.9606	0.9581	0.9475	0.9489

with YSI)						
y-intercept (comparison with YSI)	1.0401	3.2741	3.7596	3.9316	4.4485	3.8989
r^2 (comparison with YSI)	0.9228	0.9237	0.9264	0.9195	0.9231	0.9183
Slope (comparison with finger)	-	0.9880	0.9730	0.9738	0.9609	0.9645
y-intercept (comparison with YSI)	-	2.4711	3.3013	2.9576	3.3834	2.9270
R^2 (comparison with fimger)	-	0.9980	0.9966	0.9960	0.9953	0.9947

Results for glucose concentrations <75 mg/dL

	Within ±5 mg/dL	Within ± 10 mg/dL	Within ±15 mg/dL
Palm	10/13 (77%)	13/13(100%)	13/13(100%)
Forearm	11/14(79%)	13/14 (93%)	14/14 (100%)
Upper Arm	7/13 (54%)	12/13 (92%)	13/13 (100%)
Calf	9/15 (60%)	14/15 (93%)	15/15 (100%)
Thigh	12/15 (92%)	15/15 (100%)	15/15 (100%)

Results for glucose concentrations ≥ 75 mg/dL

	Within ±5 %	Within ± 10%	Within ±15 %	Within ± 20%
Palm	76/87 (87%)	85/87 (98%)	87/87(100%)	87/87 (100%)
Forearm	78/86 (91%)	84/86 (97%)	86/86 (100%)	86/86 (100%)
Upper Arm	72/87 (83%)	83/87 (95%)	86/87 (99%)	87/87 (100%)
Calf	59/85 (69%)	83/85 (98%)	84/85 (99%)	85/85 (100%)
Thigh	61/85 (72%)	83/85 (98%)	84/85 (99%)	85/85 (100%)

AG-6951 Blood Glucose Monitoring System

Alternative testing sites: palm, forearm, upper arm, calf and thigh testing were performed using 100 patient volunteers, two AG-6951 meters and 3 lots of AGS 1100 test strips. Alternative site testing was performed by the lay user and all glucose levels were collected during times of steady state conditions. The range of glucose values for these samples was 53-388 (by the finger). The linear regressions were as follows :

	Finger	Palm	Forearm	Upper Arm	Calf	Thigh

Slope (comparison with YSI)	0.973	0.986	0.9765	0.9504	0.9636	0.9478
y-intercept (comparison with YSI)	1.2477	2.0381	0.5877	4.3116	0.9825	4.0372
r^2 (comparison with YSI)	0.9838	0.9798	0.9845	0.9856	0.9903	0.9892
Slope (comparison with finger)	-	0.9623	0.9818	1.0085	1.0012	1.0157
y-intercept (comparison with YSI)	-	3.0844	2.9747	-0.7983	1.6341	-1.5139
R^2 (comparison with fimger)	-	0.9547	0.9704	0.9685	0.9767	0.9736

Results for glucose concentrations <75 mg/dL

	Within ±5 mg/dL	Within ± 10 mg/dL	Within ±15 mg/dL
Palm	8/11 (73%)	9/11 (82%)	11/11 (100%)
Forearm	7/11 (64%)	10/11 (91%)	11/11 (100%)
Upper Arm	8/11 (73%)	10/11 (91%)	11/11 (100%)
Calf	6/11 (54%)	9/11 (82%)	11/11 (100%)
Thigh	6/11 (54%)	10/11 (91%)	11/11 (100%)

Results for glucose concentrations ≥ 75 mg/dL

	Within ±5 %	Within ± 10%	Within ±15 %	Within ± 20%
Palm	38/89 (43%)	63/89 (71%)	76/89 (85%)	85/89 (96%)
Forearm	36/89 (40%)	77/89 (87%)	85/89 (96%)	89/89 (100%)
Upper Arm	40/89 (45%)	68/89 (76%)	84/89 (94%)	87/89 (98%)
Calf	44/89 (49%)	72/89 (81%)	84/89 (94%)	89/89 (100%)
Thigh	45/89 (51%)	67/89 (75%)	86/89 (97%)	88/89 (99%)

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

Time of day	People without diabetes
Fasting and before meals	<110 mg/dL
2 hours after meals	<180 mg/dL

Sponsor referenced: Joslin Diabetes Center. Goals for Blood Glucose Control. [Electronic version]. Retrieved July 5th, 2010: http://www.joslin.org/info/goals_for_blood_control.html

Labeling states: Please work with your doctor to determine a target range that works best for you.

N. Instrument Name:

AG-6081 Single Blood Glucose Monitoring System

AG-6951 Single Blood Glucose Monitoring System

AG-6081 MULTI Blood Glucose Monitoring System

AG-6951 MULTI Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:

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

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

Yes _____X___ or No _____

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:

   This device is intended to be used with capillary whole blood from the fingertip, the palm, the forearm, the upper arm, the calf, and thigh. The whole blood is applied directly to the test strip so therefore no special handling or storage is needed.

5. Calibration:

   One code function (No Code). The AGS-1100 test strips contain the calibration code. There is no coding by the user.

6. Quality Control:

   One level of glucose control solution (Level ll), is provided within the kit from the sponsor. An additional two levels Level l and Level lll are available for purchase separately, as stated in the labeling. The labeling provides instructions on when to test control materials. To perform a control test on the AG-6081 and the AG-6951 meters, the user is instructed to press the M button in step 2. Once the "CTL" appears on the screen the control results will be prevented from being stored in memory. An acceptable range for each control level is printed on the test strip vial label. If the control values fall outside these ranges, the user is referred to customer support for problems and more information.

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

1. Altitude Studies: Capillary whole blood samples from 20 volunteers with glucose concentrations, according to YSI, ranging from 61-406 mg/dL on the AG-6081 meter and 60-334 mg/dL on the AG-6951 meter. Results were compared to YSI values and resulted in no significant bias (≤ 10%) for all samples tested. The data submitted support use of the devices up to 10,744 feet.

2. Temperature and humidity studies: The sponsor performed temperature and humidity studies using the AG-6081 and the AG-6951 meters with venous whole blood samples at 5 glucose levels (44, 74, 169, 278 and 528 mg/dL). Results demonstrated that both systems (meters and test strips) can be used in conditions of 50˚-104˚F (10-40˚C) with

relative humidity 25-80% and stored under conditions of 39.0˚F -86˚F and relative humidity of <80%. No significant effect (≤ 10% relative to YSI) was observed at the temperature and humidity combinations tested. The following combinations were tested: 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 to 104˚F (10-40˚C) with relative humidity of 25-80%.

3. Sample volume studies were performed using venous blood samples 48, 55, 114,143, 226, 377, and 453 mg/dL) and of each meter (AG-6081 and AG-6951). Three volumes were tested (0.5, 0.6, and 0.7µL). The recommended minimum sample volume is 0.7µL. Seven glucose concentrations were tested ranging from approximately 48-450 mg/dL, as determined by the YSI. Results support the claimed sample volume of 0.7µL.

4. Infection Control Studies: The devices are intended for single-patient us (AG-6081 and AG-6951 Single) or multiple-patient use (AG-6081 Multi and AG-6951 Multi). 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. The sponsor provided a readability study and obtained SMOG Grade Level scores of 8 for the User's Manual, test strip insert and control solution insert.

6. Hematocrit Study - The effect of hematocrit levels of 20-65% was tested on whole blood samples spiked with nine hematocrit levels (20, 25, 30, 35, 45, 50, 55, 60, and 65%) at glucose concentrations distributed within the measuring range (20 – 600mg/dL) of the device. The values generated were compared with the glucose values from YSI-2300 analyzer. The results generated by the device are comparable to the values of YSI-2300 analyzer at hematocrit levels between 20-60%. The candidate devices did not show any significant bias (≤ ± 15%) versus the reference method within the measuring range of 20-60%. The sponsor will claim a hematocrit range of 20 -60%.

7. The sponsor provided the appropriate documentation certifying that electromagnetic testing (EMC) had been performed and the AG-6081 and AG-6951 were found compliant (IEC 61326, IEC 61010)

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.