

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

A. 510(k) Number:

k093755

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-695 Single Blood Glucose Monitoring System
AG-696 Single Blood Glucose Monitoring System
AG-695 Multi Blood Glucose Monitoring System
AG-696 Multi Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
21 CFR 862.1345, Glucose test system
2. Classification:
Class II
3. Product code:
NBW, System, Test, Blood Glucose, Over The Counter.
CGA, Glucose Oxidase, Glucose
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
See Indications for Use below.
2. Indications(s) for use:

The **AG-695 Single Blood Glucose Monitoring System** is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary blood from the fingertip. The AG-695 Single Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The AG-695 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-695 Single Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

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 AGS-1000 Single Blood Glucose Test Strips are for use with the AG-695 Single Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples.

The **AG-696 Single Blood Glucose Monitoring System** is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary blood from the fingertip. The AG-696 Single Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The AG-696 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-696 Single Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use.

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 AGS-1000 Single Blood Glucose Test Strips are for use with the AG-696 Single Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples.

The **AG-695-Multi Blood Glucose Monitoring System** is intended for the quantitative measurement of glucose in fresh capillary whole blood from the fingertip. AG-695-Multi Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended to be used by healthcare professionals for multiple patients in a professional healthcare setting as an aid in monitoring the effectiveness of a diabetes control. This system should only be used with single-use, auto-disabling lancing devices.

The AG-695-Multi Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes mellitus, nor for neonatal use

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 AGS-1000 Multi Blood Glucose Test Strips are for use with the AG-695 Multi Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples.

The **AG-696-Multi Blood Glucose Monitoring System** is intended for the quantitative measurement of glucose in fresh capillary whole blood from the fingertip. AG-696-Multi Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended to be used by healthcare professionals for multiple patients in a professional healthcare setting as an aid in monitoring the effectiveness of a diabetes control. This system should only be used with single-use, auto-disabling lancing devices.

The AG-696-Multi Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes mellitus, nor for neonatal use.

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 AGS-1000 Multi Blood Glucose Test Strips are for use with the AG-696 Multi Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples.

3. Special conditions for use statement(s):

- For in vitro diagnostic use only
- Over-the-counter and professional use

- Not intended for use on neonates
- Not for the 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 testing on the fingertip only
- Multiple-patient use devices (AG-695- multi and AG-696-multi) must be disinfected between uses following labeling recommendations.
- Multiple patient use systems should only use single use, auto disabling lancing devices.
- Single-patient use devices (AG-695 and AG-696) are for use on single-patients only and should not be shared.

4. Special instrument requirements:

The AG-695 Single and AG-696 Single meters and AGS-1000 Single Glucose Test Strips
The AG-695 Multi and AG-696 Multi meters and AGS-1000 Multi Glucose Test Strips

Disposable, single use lancing devices are used with AG-695 Multi and AG-696 Multi Blood Glucose Monitoring Systems

I. Device Description:

The AG-695 Single and AG-696 Single Blood Glucose Monitoring Systems contain a blood glucose meter (AG-695 Single or AG-696 Single, respectively), AGS-1000 Single blood glucose test strips (including a code card), Level II control solution, Owner's booklet and carrying case that are provided in the kit. Level III control solution, the adjustable lancing device, and sterile lancets are sold separately.

The AG-695 Multi and AG-696 Multi Blood Glucose Monitoring Systems contain a blood glucose meter (AG-695 Multi or AG-696 Multi, respectively), AGS-1000 Multi blood glucose test strips (including a code card), Level II control solution, Owner's booklet and carrying case that are provided in the kit. Level III control solution and auto-disabling lancing devices are sold separately.

The differences between the AG-695 Single/AG-695 Multi and the AG-696 Single/AG-696 Multi) are the memory for stored values, the averaging feature, the languages spoken, and display of the fasting blood glucose and the 2 hour post blood glucose values.

The differences between the single-patient use (AG-695 Single and AG-696 Single) and the multiple-patient use systems (AG-695 Multi and the AG-695 Multi) are in the labeling, which includes the names of the system components, disinfection instructions for using the device on single-patients versus in 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			
Item	Device AG-695 Single and AG-695 Multi Blood Glucose Monitoring Systems	Device AG-696 Single and AG-696 Multi Blood Glucose Monitoring Systems	Predicate (k073030; AG-606 Blood Glucose Monitoring System)
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
Detection Method	Amperometry	Amperometry	Same
Enzyme	Glucose oxidase	Glucose oxidase	Same
Sample Type	Fresh capillary whole blood	Fresh capillary whole blood	Same
Measuring time	5 sec	5 sec	Same
Measurement range	20-600 mg/dL	20-600 mg/dL	Same
Sample Site	Fingertip	Fingertip	Same
Measuring time	5 seconds	5 seconds	Same
Hematocrit Range	30-55%	30-55%	Same

Differences			
Item	Device AG-695	Device AG-696	Predicate (k073118)
Sample volume	0.7 μ L	0.7 μ L	1.0 μ L
Voice Function	Yes English and Chinese	Yes English and Spanish	No
Coding function	Code with a code card	Code with a code card	Enter code number

Differences			
Item	Device AG-695	Device AG-696	Predicate (k073118)
			into meter
Display the average of test results	14-, and 30-day average glucose result	7-, 14-, 28-, 60- and 90-day average glucose result	14 and 30 day average glucose result
Memory feature	350 measurement results with date and time	500 measurement results with date and time	350 measurement results with date and time
Meter dimensions (mm)	92 x 52 x 21	90 x 59 x 22	82 x 59 x 20
Weight (g) without Batteries	60	60	75
Test strip name	AGS-1000	AGS-1000	AGS- 600
Power Source	DC 3V (2xAAA)	DC 3V (2xAAA)	DC 3V (2xAAA)

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

- ISO15197:2003- *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-695 Single and AG-695 Multi are the same meters and the AG-696 Single and AG-696 Multi are the same meters. All four meters use the same test strip; however they have separate names due to single patient use and multi-patient use.

1. Analytical performance:

a. *Precision/Reproducibility:*

Within-day precision studies were performed using venous whole blood samples spiked with five different glucose concentrations, three different test strip lots, 10 different AG-695, and 10 AG-696 blood glucose meters. Each glucose level was evaluated 10 times for a total of 100 tests per each glucose level for each type of meter (AG-695 and AG-696). Results are summarized below:

Meter	AG-695	AG-696
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Sample Level (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV (%)		Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	43.8	1.9	4.42		41.1	2.4	5.95
51-110	102.9	3.3	3.26		94.7	4.1	4.28
111-150	134.5	4.7	3.53		126.4	4.6	3.68
151-250	210.9	5.5	2.63		208.6	6.7	3.23
251-400	351.1	14.7	4.19		327.0	9.7	2.96

Day-to-day precision was evaluated using three glucose control solutions with concentration levels, I (45 mg/dL), II (135 mg/dL), and III (320 mg/dL), three different reagent lots and 10 AG-695 meters and 10 AG-696 meters. These tests were performed over 10 days, for a total of 100 tests per glucose level for each meter (AG-695 and Ag-696). Results are summarized below.

Meter	AG-695			AG-696		
Control Sample	Mean (mg/dL)	SD (mg/dL)	CV (%)	Mean (mg/dL)	SD (mg/dL)	CV (%)
I (45 mg/dL)	43.6	2.0	4.57	41.0	2.8	6.85
II (135 mg/dL)	133.0	4.5	3.37	122.5	4.5	3.68
III (320 mg/dL)	340.4	10.6	3.13	339.1	9.1	2.69

b. Linearity/assay reportable range:

Linearity was evaluated using 11 spiked whole blood samples ranging in glucose concentrations from 17 to 614 mg/dL (17, 51, 76, 124, 201, 235, 311, 375, 482, 530, 614 mg/dL) as measured by YSI. Each level was measured 5 times and the values from the AG-695 meter were compared with those obtained from YSI-2300. The same evaluation was performed with the AG-696 meter with samples ranging from 19 to 607 mg/dL glucose (19, 38, 91, 146, 214, 262, 321, 400, 493, 570, 607 mg/dL) as measured by YSI. Results from regression analysis:

$$\text{AG-695 meter: } y = 0.966x + 7.7449; R^2 = 0.9984$$

$$\text{AG-696 meter: } y = 0.9783x + 2.0363; R^2 = 0.9981.$$

The claimed range of measurement for this device is 20 to 600 mg/dL glucose.

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

The sponsor claims that the system accuracy of the AG-695 and AG-696 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 2 a below.

Two levels of control material, Level II (96 to 144 mg/dL) and Level III (250 to 420 mg/dL) are available for use with this test system. These control solutions were previously cleared under k093262. The meters in the current submission use the same test strip as was previously cleared (k093262). For the current submission, value assignment was performed by testing each level of control solution 100 times using 5 of each of the meters in this submission (AG-695 and AG-696).

c. Detection limit:

The reportable range for the both the AG-695 and AG-696 Blood Glucose Monitoring Systems is 20 to 600 mg/dL. This range was verified by the linearity study (M.1.b) above.

d. Analytical specificity:

The sponsor spiked venous whole blood samples with glucose to obtain concentrations of 80, 120, and 350 mg/dL. Each of these samples was divided into a test pool and a control pool and each potential interfering substance was added to the test pool.

Each level was analyzed 5 times total with two AG-695 meters and 5 times total with two AG-696 meters with 3 lots of glucose strips. The % difference between the sample containing interfering substance and the control sample was calculated. The sponsor defines no significant interference as $\leq 10\%$ difference. Results are presented in the table below:

Potential Interfering Substance	Concentration with no Significant Interference (mg/dL)		Potential Interfering Substance	Concentration with no Significant Interference (mg/dL)
Acetaminophen	5.0		Tolazamide	30
Ascorbic Acid	2.0		Tolbutamide	64
Ephedrine	3.6		Bilirubin	15
Ibuprofen	50		Creatinine	10
L-Dopa	1.35		Uric Acid	8.0
Methyldopa	1.5		Cholesterol	500
Dopamine	0.09		Triglycerides	3000
Salicylate	60			

Higher levels of the following substances were tested and found to interfere; therefore, the following are included in the user manual and test strip insert: “the following substances at levels greater than normal or therapeutic levels may cause significant interference: acetaminophen, ascorbic acid, uric acid, dopamine and L-dopa” and “do not use icterus samples”.

Hematocrit study:

The effect of different hematocrit levels was evaluated using whole blood samples with hematocrit levels of 30, 35, 40, 45, 50 and 55% spiked with glucose to achieve 7 concentrations ranging from 21 to 598 mg/dL. Each sample was then tested in triplicate using the AG-695 meter and in triplicate using the AG-696 meter. For each sample the value obtained from the meter was compared with that obtained from the YSI-2300 analyzer. The % biases to YSI for both meters were $\leq 15\%$ for samples within the claimed range of 30 to 55% hematocrit.

- e. *Assay cut-off:*
Not Applicable.

2. Comparison studies:

- a. *Method comparison with predicate device:*

System Accuracy:

The sponsor performed accuracy studies to demonstrate that the AG-695 and AG-696 blood glucose monitoring systems are equivalent to the reference method, YSI 2300. Capillary samples from 100 volunteers were evaluated. The samples used for the AG-695 had glucose concentrations, according to YSI, ranging from 21.6 to 504 mg/dL and those used for the AG-696 ranged from 23.4 to 467 mg/dL. To obtain blood glucose concentrations <50 and >400 mg/dL, samples were allowed to glycolize or were spiked to achieve the desired glucose concentration. The results relative to YSI are summarized in the tables below:

For glucose concentrations <75 mg/dL

Meter	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
AG-695	13/20 (58%)	20/20 (100%)	20/20 (100%)
AG-696	14/19 (74%)	17/19 (89%)	18/19 (95%)

For glucose concentrations ≥ 75 mg/dL

Meter	within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
AG-695	47/80 (59%)	73/80 (91%)	79/80 (99%)	80/80 (100%)
AG-696	37/81 (46%)	69/81 (85%)	78/81 (96%)	80/81 (99%)

Regression Analysis vs. YSI

Comparison	N	Slope and y-intercept	R ²
AG-695 vs. YSI	100	y=1.01x-1.7322	0.9894
AG-696 vs. YSI	100	y=1.004x+2.0119	0.9855

User Performance Study:

To demonstrate the accuracy of the AG-695 and AG-696 blood glucose monitoring systems the sponsor performed a study for each of the meters with 100 lay user

participants and one technician at four different hospitals. The participants, who were able to read the User's Manual in English were instructed to read the manual, obtain their own finger stick sample and perform testing using the meter (AG-695 or AG-696). The technician then performed the testing on an additional fingerstick sample from the user. The samples ranged from 50 to 345 mg/dL for the AG-695 and 52 to 360 mg/dL for the AG-696. A sample was then taken from each participant by the technician and measured by YSI-2300. The results are summarized in the tables below:

Lay-user vs. YSI:

For glucose concentrations <75 mg/dL

Meter	within \pm 5 mg/dL	within \pm 10 mg/dL	within \pm 15 mg/dL
AG-695	4/6 (67%)	6/6 (100%)	6/6 (100%)
AG-696	4/6 (67%)	5/6 (83%)	6/6 (100%)

For glucose concentrations \geq 75 mg/dL

Meter	within \pm 5 %	within \pm 10 %	within \pm 15 %	within \pm 20 %
AG-695	36/94 (38%)	79/94 (84%)	89/94 (95%)	94/94 (100%)
AG-696	28/94 (30%)	77/94 (82%)	90/94 (96%)	94/94 (100%)

Technician vs. YSI:

For glucose concentrations <75 mg/dL

Meter	within \pm 5 mg/dL	within \pm 10 mg/dL	within \pm 15 mg/dL
AG-695	3/6 (50%)	6/6 (100%)	6/6 (100%)
AG-696	4/6 (67%)	5/6 (83%)	6/6 (100%)

For glucose concentrations \geq 75 mg/dL

Meter	within \pm 5 %	within \pm 10 %	within \pm 15 %	within \pm 20 %
AG-695	34/94 (36%)	75/94 (80%)	93/94 (99%)	94/94 (100%)
AG-696	44/94 (47%)	86/94 (91%)	94/94 (100%)	94/94 (100%)

Linear Regression Analysis:

Comparison	N	Slope and y-intercept	R ²
Lay user AG-695 vs. YSI	100	y=1.0153x-0.60	0.9798
Technician AG-695 vs. YSI	100	y=1.0231x-0.4236	0.9817
Lay user AG-696 vs. YSI	100	y=1.012x+3.5277	0.9844
Technician AG-696 vs. YSI	100	y=1.0094x+1.6481	0.988

Visually Impaired User Study:

The sponsor performed a visually impaired user study with 100 participants with visual impairments ranging from moderate to profound with vision categories from 0.02 to 0.3 according to the ICD-9 World Health Organization classification. The

users performed their own finger sticks and performed the test by following a large print user's manual in English for the meter (AG-695 or AG-696). The technician then performed the testing on an additional fingerstick sample from each user. A sample was then taken from each participant by the technician and measured by YSI-2300. The samples ranged from 53.9 to 324 mg/dL glucose as measured by YSI. 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.

Visually impaired lay-user vs. YSI:

For glucose concentrations <75 mg/dL

Meter	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
AG-695	10/17 (59%)	17/17 (100%)	17/17 (100%)
AG-696	8/17 (47%)	17/17 (100%)	17/17 (100%)

For glucose concentrations ≥ 75 mg/dL

Meter	within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
AG-695	35/83 (42%)	66/83 (80%)	81/83 (98%)	83/83 (100%)
AG-696	35/83 (42%)	70/83 (84%)	81/83 (98%)	83/83 (100%)

Technician vs. YSI:

For glucose concentrations <75 mg/dL

Meter	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
AG-695	7/17 (41%)	17/17 (100%)	17/17 (100%)
AG-696	9/17 (53%)	17/17 (100%)	17/17 (100%)

For glucose concentrations ≥ 75 mg/dL

Meter	within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
AG-695	36/83 (43%)	70/83 (84%)	82/83 (99%)	83/83 (100%)
AG-696	33/83 (40%)	70/83 (84%)	81/83 (98%)	83/83 (100%)

Linear Regression Analysis:

Comparison	N	Slope and y-intercept	R ²
Lay user AG-695 vs. YSI	100	y=0.9903x+6.1175	0.9726
Technician AG-695 vs. YSI	100	y=0.9563x+7.5832	0.9768
Lay user AG-696 vs. YSI	100	y=0.9678x+5.8518	0.977
Technician AG-696 vs. YSI	100	y=0.9642x+5.6125	0.9767

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):*

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

The sponsor references: Joslin Diabetes Center. Goals for Blood Glucose Control. [Electronic version]. Retrieved July 5th, 2010:
http://www.joslin.org/info/goals_for_blood_glucose_control.html

The labeling includes the following statement: Please work with your doctor to determine a target range that works best for you.

N. Instrument Name:

- AG-695 Single Blood Glucose Monitoring System
- AG-696 Single Blood Glucose Monitoring System
- AG-695 Multi Blood Glucose Monitoring System
- AG-696 Multi Blood Glucose Monitoring System,

O. System Description:

1. Modes of Operation:

Each test strip is single use and must be replaced 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 ___ 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:

This device is intended to be used with capillary whole blood from the fingertip. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

The meter uses a code strip. To code the meter the code strip is inserted into the meter. Once the "OK" appears on the screen, the meter is coded and the code strip can be removed.

6. Quality Control:

The sponsor provides one level of glucose control solution, Level II (cleared under k093262), with this kit. Additional (Level III) control solution (also cleared under k093262), is also available for purchase separately, as stated in the labeling. The labeling provides recommendations on when to test control materials. To perform a control test the user is instructed to press the S button in step 5. Once the "CTL" appears on the screen the control results will be prevented from being stored in the 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 70 to 415 mg/dL for the AG-695 meter and 68 to 395 mg/dL for the AG-696 meter were measured at 11,975 feet (3650 meters). All individual measurements resulted in % biases less than +/-10% relative to the YSI value. The results support the claims in the labeling that altitudes up to 11,975 feet have no significant effect (relative to YSI) on blood glucose measurements from the AG-695 and AG-696 meters.

2. Temperature and humidity studies: The sponsor performed temperature and humidity studies using venous blood samples (with glucose concentrations of 52, 168 and 418 mg/dL) and 3 of each meter (AG-695 and the AG-696). Several temperatures ranging from 50 to 104°F (10 to 40°C) to and relative humidity of 10 to 90% were tested and meter results compared to YSI values. Six temperature and humidity combination were tested including low temperature/low humidity, low temperature/high humidity, high temperature/low humidity, and high temperature/high humidity. Results demonstrated that both devices can be used in conditions of 50 to 104°F (10 to 40°C) with relative humidity below 90% and stored at 39 to 86°F and relative humidity below 85%. No significant effect (relative to YSI) was observed at the temperature and humidity combinations tested. The results support the claims in the labeling that the system can be used can be used in conditions of 50 to 104°F (10 to 40°C) with relative humidity of 10 to 90%.
3. Insufficient and excessive sample volume studies were performed using venous blood samples (approximately 45, 55, 115, 140, 230, 376, and 453 mg/dL) and 3 of each meter (AG-695 and AG-696). Five were tested (0.5, 0.6, 0.7, 1.0 and 1.5 µL) were tested around the recommended sample volume of 0.7 µL. Seven glucose concentrations were tested ranging from approximately 45-450 mg/dL, as determined by the YSI. Results support the claimed sample volume of 0.7 µL.
4. Infection Control Studies: The devices are intended for single-patient use (AG-695 Single and AG-696 Single) or multiple-patient use (AG-695 Multi and AG-696 Multi). Disinfection efficacy studies were performed on the materials comprising the meters and lancing device by an 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 CaviWipes. The robustness studies were designed to simulate 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. The sponsors provided the appropriate documentation certifying that electromagnetic testing (EMC) had been performed and the AG-695 and AG-696 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.