

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

A. 510(k) Number:

k052762

B. Purpose for Submission:

Premarket Notification 510(k) of intention to manufacture and market the AgaMatrix Liberty™ Blood Glucose Monitoring System.

C. Measurand:

Whole Blood Glucose

D. Type of Test:

Quantitative, utilizing Glucose Oxidase technology

E. Applicant:

AgaMatrix, Inc.

F. Proprietary and Established Names:

Liberty™ Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1345, Glucose test system.

21 CFR §862.1660, Single (Specified) Analyte Controls (Assayed and Unassayed)

2. Classification:

Class II (analyte)

Class I (controls)

3. Product code:

NBW, CGA (glucose)

JJX (control)

4. Panel:

75 (Chemistry)

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

AgaMatrix Liberty™ Blood Glucose Monitoring System:

AgaMatrix Liberty™ Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the fingertip and palm of the hand. Testing is done outside the body (in vitro diagnostic use). It is intended for use at home (over the counter (OTC)) by persons with diabetes, or in a clinical setting by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

AgaMatrix Liberty™ Blood Glucose Meter:

AgaMatrix Liberty™ Blood Glucose meter is intended for use with AgaMatrix Liberty™ Blood Glucose Test Strips for the quantitative measurement of glucose in fresh capillary whole blood from the fingertip and palm of the hand. Testing is done outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter (OTC)) by persons with diabetes, or in a clinical setting by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

AgaMatrix Liberty™ Blood Glucose Test Strips:

AgaMatrix Liberty™ Blood Glucose Test Strips are intended for use with AgaMatrix Liberty™ Blood Glucose Meter for the quantitative measurement of glucose in fresh capillary whole blood from the fingertip and palm of the hand. Testing is done outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter (OTC)) by persons with diabetes, or in a clinical setting by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

AgaMatrix Liberty™ Control Solution:

AgaMatrix Liberty™ Control Solution is intended for use with AgaMatrix Liberty™ Meter and AgaMatrix Liberty™ Test Strips as a quality control check to verify the accuracy of blood glucose test results.

3. Special conditions for use statement(s):

Provides plasma equivalent results.
This device is not intended for use on neonates.

4. Special instrument requirements:

Liberty™ Blood Glucose Monitoring System

I. Device Description:

The AgaMatrix Liberty™ Blood Glucose Monitoring System includes a meter with batteries, compact carrying case, quick start guide, reference guide, owner’s booklet, and warranty/registration card. Test Strips, Lancing device, Lancets, and Control Solution are purchased separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bayer Ascensia Contour Blood Glucose Monitoring System

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

k023657

3. Comparison with predicate:

Similarities		
Item	Predicate Device Ascensia Contour k023657	New Device AgaMatrix Liberty™ k052762
Intended Use	Blood glucose monitoring for home and point-of-care	Same
Calibration	Plasma equivalent	Same
Operating Temperature	50-104 F (10-40 C)	Same
System Components	Meter, test strip, control solution	Same
Specimen	Whole blood, capillary	same
Blood Sampling Sites	Fingertip, palm	Same
Measurement Units	mg/dL or mmol/L	Same
Hematocrit Range	20-60%	Same
Calibration	Plasma equivalent	Same
Power Source	2#2032, 3 volt lithium batteries, replaceable	Same

Differences		
Item	Predicate Device Ascensia Contour k023657	New Device AgaMatrix Liberty™ k052762
Test Principle/ Enzyme	Electrochemical, Glucose dehydrogenase	Electrochemical. Glucose Oxidase
Test Range	10-600 mg/dL	20-600 mg/dL
Sample Volume	0.6 microliters	0.5 microliters
Test Time	15 seconds	Minimum of 4 seconds, maximum of 12 seconds
Cal code setting	Automatic	Manual
Backlight	No	Yes
Number of test results stored	240	300
Size	5.3” (width) x 7.4” (length) x 1.73” (height)	4.0” (width) x 7.0” (length) x 1.4” (height)
Weight	52.3 g (including batteries)	44.1 g (including batteries)

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

The manufacturer of the Liberty™ Blood Glucose Monitoring System certifies that its device complies with the following:

ISO 15197: 2003 In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus.

ISO 14971: 2000 Medical devices – Application of risk management to medical devices.

IEC 61010-1 Medical electrical equipment – General requirements for safety.

IEC 61010-2-101 Safety requirements for electrical equipment for measurement, control and laboratory use – particular requirements for in vitro diagnostic (IVD) medical equipment.

IEC 61000-4-3 Electromagnetic compatibility (EMC).

NCCLS EP5 Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline.

L. Test Principle:

The Test Principle used by this device is electrochemical biosensor technology using Glucose Oxidase. The strip uses the enzyme Glucose Oxidase to produce an electrical current that will stimulate a chemical reaction. This reaction is measured by the Liberty™ meter and displayed as a blood glucose result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

According to the sponsor repeatability testing was done according to ISO 15197. Repeatability was evaluated using at least 10 meters, one lot of test strips, and using whole blood samples at 5 glucose concentrations analyzed at least 10 times each within one day on each meter.

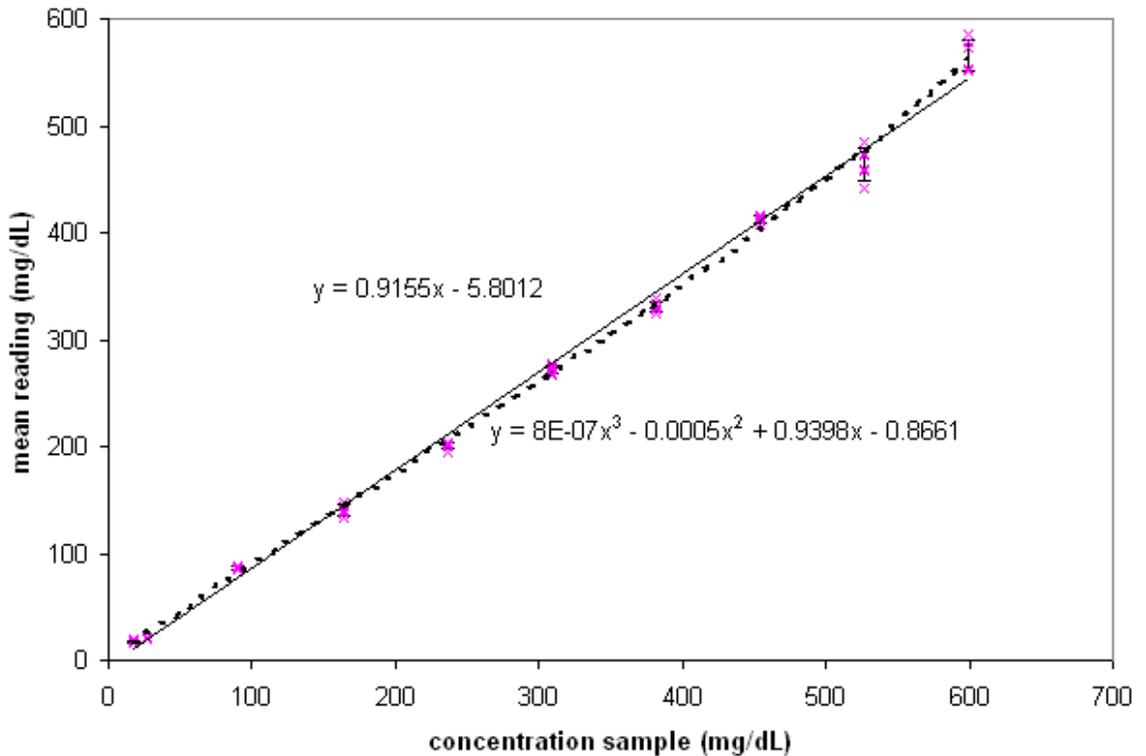
All data gathered from the 5 blood samples was considered acceptable. See table below:

Glucose mg/dL		1	2	3	4	5	6	7	8	9	10
50	Mean	43.9	46.8	43.7	45.1	46.2	46	45.1	47.4	46.2	43.8
	SD	1.8	2.1	1.6	1.3	1.8	2.3	1.8	1.5	1.6	1.6
	CV	4.1%	4.5%	3.7%	2.9%	3.8%	4.9%	4.0%	3.2%	3.5%	3.7%
91	Mean	89.3	93.7	90.0	91.9	91.1	90.0	90.9	94.7	91.9	89.9
	SD	1.9	4.4	2.0	3.3	2.3	4.6	2.0	2.8	2.8	2.6
	CV	2.1%	4.7%	2.2%	3.6%	2.5%	5.0%	2.2%	3.0%	3.1%	2.8%
125	Mean	122.9	123.7	120	120.9	122.7	121	121.8	130.8	122.8	121.7
	SD	3.6	1.7	2.8	2.8	3.3	2.5	2.8	3.3	4.8	3.3
	CV	3.0%	1.4%	2.4%	2.4%	2.7%	2.1%	2.3%	2.5%	3.9	2.7%
225	Mean	215.6	218.1	211.4	210.2	212.5	211.1	214.7	226.4	218.2	215.3
	SD	8.0	3.9	2.5	3.7	4.6	4.8	4.9	5.2	5.4	4.8
	CV	3.7%	1.8%	1.2%	1.8%	2.2%	2.3%	2.3%	2.3%	2.5%	2.2%
291	Mean	276.6	283.2	273.5	276.8	276.3	270.6	263.4	282.3	273.3	269.1
	SD	9.7	8.6	5.7	12.9	13.7	9.0	5.9	8.2	7.6	5.1
	CV	3.5%	3.0%	2.1%	4.7%	5.0%	3.3%	2.2%	2.9%	2.8%	1.9%

b. *Linearity/assay reportable range:*

According to the sponsor the evaluation of analytical performance of the Liberty blood glucose monitoring system consists of several parts and the evaluation of the linearity of readings is one of these parts. The method to assess the accuracy of measurements on blood samples with a wide range of standard properties is defined in the Liberty Linearity Evaluation Protocol. Included in this testing protocol are descriptions of how the results it generates are to be assessed.

High and Low samples were prepared to glucose concentrations slightly higher than that desired before being placed in the tonometer. The prepared samples had dropped to near the desired values by the time they had equilibrated, and were mixed to generate the desired range of linearity samples. There were six data points collected for every sample prepared. The data, presented below shows neither extreme non-linearity nor outliers.



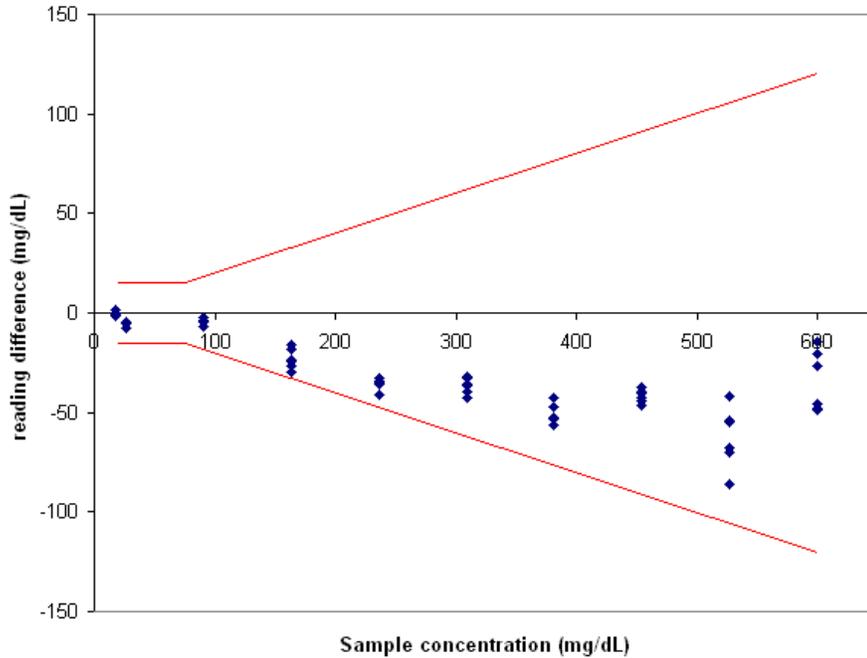
Linearity data plotted as test method (y-axis) against sample glucose (x-axis). Linear- and 3rd-order polynomial -least-squares regression curves are fitted to the data (solid and dotted lines respectively); see below. The data is shown as individual points (crosses) with error bars marking the standard error limits of the mean.

Difference plot

The difference between the meter reading and the sample glucose concentration is subject to system accuracy limits within the Test Range of the meter. The system accuracy is assessed according to the Liberty Product Requirements Document (PRD) the section of the PRD relevant to this work is listed in the table below. This section defines performance requirements according to ISO requirements:

Factor investigated	Section of PRD	Requirement
Plasma glucose concentration (Plasma glucose)	5.2.4 Test Range	The meter and test strip shall be able to test blood glucose levels between 20-600 mg/dL (1.1 – 33.3 mmol/L).
System accuracy	6.2.3 System accuracy requirements	<p>The requirements of ISO 15197 apply for samples, reagent system, meters, environment, procedure, general data analysis, data presentation, system accuracy analysis, regression analysis, and minimum acceptable system accuracy.</p> <p>System accuracy shall be evaluated with blood samples according to ISO 15197; ninety-five percent (95 %) of the individual glucose results shall fall within ± 15 mg/dL (± 0.83 mmol/L) of the results of the manufacturer's measurement procedure at glucose concentrations < 75 mg/dL (< 4.2 mmol/L) and within $\pm 20\%$ at glucose concentrations ≥ 75 mg/dL (3.9 mmol/L).</p>

The data collected for this report cover the range 0.99 to 33.3 mM glucose and show that the system accuracy is maintained within ISO requirements across the full Test Range. This is shown in the difference plot below:



Difference plot between sample concentration (x-axis) and difference in sample concentration and reading (y-axis). The ISO limits are shown as solid red lines and all data is within these limits.

Regression Analysis

The data are to be assessed for linearity across the test range according to NCCLS EP6-A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guidelines and the system accuracy were also assessed according to the Liberty Product Requirements Document. The results of least-squares regression are listed in the table:

order	coefficient	value	s.e.	t-test parameters				Standard error regression
				Value /s.e.	Degrees of freedom	t-value	conclusion	
1st	b0	-5.80	2.84					12.67
	b1	16.48	0.15					
2nd	b0	5.29	3.04					10.27
	b1	14.00	0.46					
	b2	0.076	0.014	5.58	57	2.002	significant	
3 rd	b0	-0.87	3.55					9.65
	b1	16.92	1.09					
	b2	-0.150	0.078	-1.91	56	2.003	not significant	
	b3	0.0045	0.0015	2.92	56	2.003	significant	

Parameters determined for use in the t-test are listed in the above table and show that both the second- and third-order polynomials have significant coefficients of non-linearity and are therefore candidates for description of system performance. Of these two polynomials, the standard error of regression shows the third-order polynomial to be the better candidate. The difference between the linear (first-order) and third-order polynomial are calculated in the table below for all sample concentrations encountered:

concentration		Predicted values		Deviations from linearity, 1 st – 3 rd	
mM	mg/dL	1 st order	3 rd order	Absolute, mg/dL	%
33.3	600	543	561		2.98
29.3	527	477	478		0.19
25.2	454	410	402		-1.75
21.2	382	343	333		-2.83
17.2	309	277	268		-2.99
13.1	236	210	205		-2.16
9.1	163	144	144		-0.08
5.0	91	77	81		4.30
1.47	26.5	18.5	23.7	5.3	
0.99	17.8	10.5	15.8	5.2	

The differences between the linear and non-linear models, when judged against the criteria set for system accuracy, show deviations to be small. The final step defined in NCCLS EP6-A to establish linearity is to check the repeatability for these measurements. Repeatability is expressed in absolute terms for concentrations below 75 mg/dL and relative terms above, in line with the system accuracy requirements defined in ISO 15197, which require less than 15 mg/dL error below this point and less than 20% error above it.

concentration		Deviations from linearity, 1 st – 3 rd		Repeatability	
mM	mg/dL	Absolute, mg/dL	%	SD mg/dL	CV %
33.3	600		2.98		2.67
29.3	527		0.19		3.32
25.2	454		-1.75		0.81
21.2	382		-2.83		1.51
17.2	309		-2.99		1.53
13.1	236		-2.16		1.44
9.1	163		-0.08		3.48
5.0	91		4.30		2.13
1.47	26.5	5.3		1.5	
0.99	17.8	5.2		1.4	

Given the small deviations from linearity and the tight repeatability, the system is considered to be linear across its full Test Range.

Summary of linearity

For measurement of plasma glucose concentrations in whole blood by the AgaMatrix Liberty Blood Glucose Monitoring System the method has been demonstrated to be linear from 20 mg/dL (1.1 mM) to 600 mg/dL (33.3 mM), within the accuracy limits of 4.5% above 75 mg/dL (4.2 mM) and 6 mg/dL (0.83 mM) below this point.

Summary of system accuracy

The results for system accuracy for glucose concentrations between 20 and 75mg/dL are tabulated below:

Within \pm 5mg/dL	Within \pm 10mg/dL	Within \pm 15mg/dL
2/6 (33 %)	6/6 (100%)	6/6 (100%)

And the results for system accuracy for glucose concentrations between 75 and 600 mg/dL are:

Readings			
Within \pm 5%	Within \pm 10%	Within \pm 15%	Within \pm 20%
6/48 (13%)	19/48 (40%)	43/48 (90%)	48/48 (100%)

Combining these results gives 100% of data within the required limits (within \pm 15 mg/dL of the results of the manufacturer's measurement procedure at glucose concentrations < 75 mg/dL and within \pm 20 % at glucose concentrations < 75 mg/dL).

Success of the assessment

The plasma glucose concentration requirement, that the meter and test strip shall be able to test blood glucose levels between 20-600 mg/dL (1.1 – 33.3 mmol/L), has been satisfied.

The requirement for system accuracy defined in section 6.2.3 of the PRD and section 7.4 of ISO15197:2003 are met because 100% of data recorded as part of the protocol falls within the required limits.

Linearity has been demonstrated according to the method defined in NCCLS EP6-A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guidelines.

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

The traceability of the AgaMatrix Liberty Blood Glucose Monitoring System is referenced to the YSI 2300 Stat Plus glucose analyzer. The YSI 2300 glucose reference method was used by AgaMatrix to calibrate the Liberty system to yield plasma equivalent glucose concentrations when measuring capillary whole blood samples. The YSI 2300 is also the reference method used in this study to assess the accuracy with which glucose results are obtained using the Liberty system.

The glucose standard is referenced to the National Institute of Standards and Technology (NIST) Standard Reference Material (SRM) 917A, NIST-certified volumetric glassware, and balances calibrated with NIST traceable mass standards.

Additional traceability of the Liberty Blood Glucose Monitoring System to the primary reference method for plasma glucose is accomplished by periodic analysis at AgaMatrix of NIST SRM 965a serum glucose controls (4 levels) which contain NIST-certified isotope dilution mass spectrometry target values. Data available at AgaMatrix demonstrate a high level of agreement between the methods. The precision of the YSI 2300 analyzer observed during analyses of SRM 965a is typically between 0.5 to 2.0% CV at all levels of glucose tested.

d. Detection limit:

According to the sponsor High and Low blood samples were prepared to glucose concentrations slightly higher than that desired before being placed in the tonometer. The prepared samples had dropped to near the desired values by the time they had equilibrated, and were mixed to generate the desired range of (20 – 600 mg/dL). Readings were taken on the Low sample first because it was already just beyond the limit of the meter’s test range. However, when measuring the Low sample, the screen readings all displayed “LO”, indicating values below 20 mg/dL, and values had to be recorded electronically off the meter. YSI measurements of the final sample properties confirmed the samples had values below the test range of the meter. The sponsor prepared a ninth sample by mixing aliquots from the Low and High blood sample, and readings were obtained as listed in the table below.

Glucose reading on YSI	Sample	
	Low readings	High readings
YSI white (mg/dL)	19.2	604
YSI black (mg/dL)	20.5	592
YSI average (mM)	1.10	33.2

Sample	Readings						Comments
	1	2	3	4	5	6	
							Numbers in

Low	Lo (19)	Lo (16)	Lo (19)	Lo (16)	Lo (18)	Lo (17)	parentheses recorded off meter
7	140	139	137	145	134	147	
3	417	408	412	414	410	415	
8	84	86	88	84	87	88	
5	269	276	266	277	273	272	
High	551	573	579	552	554	585	
2	459	473	441	457	485	472	
6	200	201	203	195	202	202	
4	334	329	339	325	329	328	
9	21	Lo (19)	22	Lo (19)	Lo (19)	22	Sample 9 prepared from Low and High

Detection Limit has been determined as 20-600 mg/dL.

e. Analytical specificity:

According to the sponsor data was analyzed for chemical interference according to the guidelines given by NCCLS document EP7-A or equivalent apply.

Interference requirements:

Interference from bilirubin shall be <10% at a level of 15 mg/dL of bilirubin

Interference from uric acid shall be <10% at a level of 9 mg/dL uric acid.

Interference from acetaminophen shall be <10% at a level of 10 mg/dL acetaminophen.

Interference from triglycerides shall be <10% at a level of 500 mg/dL triglycerides.

Interference from ascorbic acid shall be <10% at a level of 5 mg/dL ascorbic acid.

Results of Interference Testing

The bilirubin interference requirement **is satisfied** for both conjugated and unconjugated bilirubin.

The uric acid interference requirement **is satisfied**.

The acetaminophen interference requirement **is satisfied**.

The Triglyceride interference requirement **is satisfied**.

The ascorbic acid interference requirement is **not satisfied**.

*** Based on the results of the ascorbic acid interference test, the results indicate that the maximum level of ascorbic acid interference that may be tolerated to result in at most 10% bias is 2.0 mg/dL at a glucose level of 85 mg/dL. The recommendation based on this test is to change the Product Requirement Document (PRD) to reflect that the maximum level of ascorbic acid interference that should be claimed is 2.0 mg/dL.**

f. Assay cut-off:

Not Applicable for this type of device.

2. Comparison studies:

a. *Method comparison with predicate device:*

According to the sponsor the lay user blood glucose results obtained with the Liberty System were compared to the Health Care Provider (HCP) results obtained with the Liberty System and linear regression analysis was performed. The number of data points (n), the slope and its 95% confidence interval (95%CI), the y-intercept and its 95% confidence interval, the standard error of the estimate (Sy.x), and the correlation coefficient (r) are summarized for all three sites in the table below.

In a similar manner, the lay user blood glucose results obtained with the Liberty System were compared to the YSI reference method results, and the HCP results obtained with the Liberty System were also compared to the YSI reference results. Linear regression analyses were performed and the results for both comparisons at each of the three sites. The table below was expanded to include **range of x-value** (YSI) and **range of y-values** (Liberty) for all method comparisons. All the comparison data were for samples taken from the **finger**.

Summary of Method Comparisons and Linear Regression Data

Lo t #	Comparison	n	Slope (95% CI)	y-Int (95% CI)	Sy.x	r	Range of x-values mg/dL	Range of y-values mg/dL
A	Lay user vs. HCP	60	0.97 (0.93 to 1.01)	2.3 (-5.1 to 9.8)	13.7	0.989	77-549	72-555
	HCP vs. YSI ref.	57	1.01 (0.97 to 1.06)	-1.4 (-9.8 to 7.0)	15.1	0.987	63-487	77-549
	Lay user vs. YSI ref.	58	1.00 (0.96 to 1.05)	-1.4 (-10.3 to 7.5)	16.1	0.985	63-487	72-555
B	Lay user vs. HCP	53	1.01 (0.98 to 1.05)	-2.29 (-9.0 to 4.4)	11.1	0.993	66-477	56-505
	HCP vs. YSI ref.	51	0.92 (0.88 to 0.96)	11.9 (4.4 to 19.4)	12.7	0.990	57-535	66-477
	Lay user vs. YSI ref.	51	0.94 (0.91 to 0.97)	8.14 (2.8 to 14.0)	9.84	0.994	57-535	56-505
C	Lay user vs. HCP	53	1.01 (0.96 to 1.05)	3.59 (-5.5 to 12.7)	14.3	0.986	44-388	42-383
	HCP vs. YSI ref.	51	0.89 (0.85 to 0.94)	9.13 (0.50 to	13.5	0.987	52-424	44-388

				17.8)				
	Lay user vs. YSI ref.	51	0.90 (0.85 to 0.95)	11.6 (2.0 to 21.1)	14.9	0.984	52-424	42-383

The user study method comparison data for the three clinical sites was expanded to include **range of x-values** (YSI) and **range of y-values** (Liberty) for all method comparisons. All the comparison data were for samples taken from the **finger**.

Summary of combined user study method comparisons and linear regression data

Lo t #	Comparison	n	Slope (95% CI)	y-Int (95% CI)	Sy.x	r	Range of x-values mg/dL	Range of y-values mg/dL
A,	Lay user vs. HCP	166	0.99 (0.97 to 1.02)	1.42 (-3.08 to 5.93)	13.4	0.989	44-549	42-555
B,	HCP vs. YSI ref.	159	0.94 (0.92 to 0.97)	6.53 (1.45 to 11.6)	15.1	0.985	52-535	44-549
C,	Lay user vs. YSI ref.	160	95 (0.92 to 0.97)	5.83 (0.97 to 10.7)	14.5	0.987	52-535	42-555

b. Matrix comparison:

Liberty Glucose from Palm by User vs. Liberty Glucose from Fingertip by HCP

Alternate site comparisons studies obtained by the lay users on blood samples taken from the palm of the hand were compared to glucose results obtained by Health Care Provider (HCP) on blood samples taken from the fingertip. It was found that 98% of the results obtained by users on blood samples taken from the palm of their hands (51/52*) were within the clinically accurate zone A on consensus error grid analysis when compared to the results obtained by (HCP) on blood taken from the fingertip. The remaining result fell into the clinically acceptable zone B.

Linear regression analysis was performed and the linear regression equation and 95% confidence interval for the slope and y-intercept for this Liberty user palm vs. Liberty HCP fingertip comparison data are:

$$y = 0.98x (0.92 \text{ to } 1.03) + 6.8 (-2.4 \text{ to } 16.1), \text{ with } S_{y.x} = 14.7 \text{ and } r = 0.982.$$

There was a between method outlier detected in this data set according to NCCLS EP9-A2: for the sample of ID# 14 the user palm and HCP finger results were 194 mg/dL and 293 mg/dL respectively. The point was excluded from the linear regression but was included in the consensus error grid analysis.

Liberty Glucose from Palm by HCP vs. Liberty Glucose from Fingertip by HCP

Glucose results obtained by a HCP on blood samples taken from the palm of the hand were compared to the glucose results obtained by a HCP on blood samples taken from the fingertip. It was found that 96% of the results obtained by the HCP on blood samples taken from the palm of the hand (50/52*) were within the clinically accurate zone A on consensus error grid analysis when compared to the results obtained by the HCP on blood obtained from the fingertip. The 2 remaining results fell into the clinically acceptable zone B. Linear regression analysis was performed and the linear regression equation and 95% confidence interval for the slope and y-intercept for this Liberty HCP palm vs. Liberty HCP fingertip comparison data are:

$$y = 0.97x (0.89 \text{ to } 1.05) + 5.0 (-7.8 \text{ to } 17.7), \text{ with } S_{y.x} = 16.0 \text{ and } r = 0.962.$$

There is missing data for one sample in this data set: for one sample (ID# 10) an insufficient sample was applied to the test strip as visually detected for the HCP palm measurement and on a second attempt an Er4 message was obtained for this HCP palm result. The Er4 message is displayed when insufficient blood is applied to the test strip.

Liberty Glucose from Palm by Lay User vs. YSI Fingertip by HCP

Glucose results obtained by lay users on blood samples taken from the palm of the hand were compared to the plasma glucose results obtained using the YSI reference method by an HCP on blood samples taken from the fingertip. It was found that 96% of the Liberty results obtained by the user on blood samples taken from the palm of the hand (48/50) were within the clinically accurate zone A on consensus error grid analysis when compared to the YSI plasma glucose results obtained by an HCP on blood taken from the fingertip. The remaining 2 results fell into the clinically acceptable zone B. Linear regression analysis was performed and the linear regression equation and 95% confidence intervals for the slope and y-intercept for this Liberty user palm vs. YSI plasma glucose from fingertip comparison data are:

$$y = 0.95x (0.90 \text{ to } 1.01) + 9.3 (-0.8 \text{ to } 19.3), \text{ with } S_{y.x} = 16.0 \text{ and } r = 0.979.$$

There is missing data for three samples in this data set: for two samples (ID# 21 and ID# 40) there was insufficient sample for YSI measurement; for one sample (ID# 8) an ER4 message was obtained for the user palm result. The ER4 message is displayed when insufficient blood is applied to the test strip.

Liberty Palm by HCP vs. YSI Fingertip

Glucose results obtained by the HCP on blood samples taken from the palm of the hand were compared to the plasma glucose results obtained using the YSI reference method by a HCP on blood samples taken from the fingertip. It was found that 98% of the Liberty results obtained by the HCP on blood samples taken from the palm of the hand (49/50*) were within the clinically accurate zone A on consensus error grid analysis when compared to the YSI plasma glucose results by an HCP on blood taken from the fingertip. The remaining 1 result fell into the clinically acceptable zone B. Linear regression analysis was performed** and the linear regression equation and 95% confidence intervals for the slope and y-intercept for this Liberty HCP Palm vs. YSI plasma glucose from fingertip comparison data are:

$$y = 0.96x (0.89 \text{ to } 1.04) + 6.4 (-6.4 \text{ to } 19.1), \text{ with } S_{y.x} = 15.9 \text{ and } r = 0.963.$$

**While there were no statistical outliers in this data set, inspection of the data reveals that one data point is influential on the linear regression analysis. This point (ID# 5: 409 mg/dL for HCP palm and 526 mg/dL for YSI fingertip) had a higher glucose concentration than all of the rest of the points in the data set (next highest glucose concentration for YSI fingertip was 278 mg/dL). It was determined that the better estimate of slope and intercept for this comparison data would be obtained by exclusion of this data point from the linear regression analysis. This point was included in the error grid analysis. See summary chart below.

Liberty Clinical Summary Alternate Site (Palm) Study

Comparison	n	Slope (95% CI)	y-Int (95% CI)	Sy.x	r	Range of x-values mg/dL	Range of y-values mg/dL
KeyNote Palm by User vs. KeyNote Fingertip by HCP	51	0.98 (0.92 to 1.03)	6.8 (-2.4 to 16.1)	14.7	0.982	62-537	69-521
KeyNote Palm by HCP vs. KeyNote Fingertip by HCP	51	0.97 (0.89 to 1.05)	5.0 (-7.8 to 17.7)	16.0	0.962	62-293 (537*)	43-292 (409*)
KeyNote Palm by User vs. YSI Fingertip	50	0.95 (0.90 to 1.01)	9.3 (-0.8 to 19.3)	16.0	0.979	59-526	69-521
KeyNote Palm by HCP vs. YSI Fingertip	49	0.96 (0.89 to 1.04)	6.4 (-6.4 to 19.1)	15.9	0.963	61-278 (526*)	43-292 (409*)

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:

The Liberty Meter and Target ranges are referenced from literature source: ADA Clinical Practice Recommendations 2003.

Time of Day	Glucose Ranges for People Without Diabetes (mg/dL)
Before Meals	70-110
1 Hour After Meals	Less Than 160
2 Hours After Meals	Less Than 120
Between 2 am and 4 am	Greater Than 70

N. Instrument Name:

Liberty™ Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:

The Liberty™ Blood Glucose Monitoring System used with the Liberty™ Test Strips is a single use test system used to quantitatively measure blood glucose levels, also known as blood sugar, from fresh capillary whole blood samples taken from the fingertips or the palm. The Liberty™ Test Strips are for in vitro diagnostic use only. The Liberty™ Blood Glucose Monitoring System is not intended for use with neonates.

2. Software:

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

Yes ___X___ or No _____

3. Specimen Identification:

The Liberty™ meter stores the last 300 test results with time and date. If the memory is full, the oldest test result will be deleted and a new test result will be stored in its place. The Liberty™ Meter calculates averages of all the test results during breakfast, lunch, dinner and bedtime. Control solution, Hi and Lo test results, out-of-temperature range

results, and results without a valid date/time are not included in the average. This system does not provide sample identification, but provides real time single use results to the user. The Liberty™ Meter can provide 14, 30, and 90 Day Trend Graphs.

Breakfast averages include glucose measurements between 4:00 am and 10:00 am, lunch averages are between 10:00 am and 4:00 pm, dinner averages are between 4:00 pm and 10:00 pm, and bedtime averages are between 10:00 pm and 4:00 am.

4. Specimen Sampling and Handling:

Testing on Fingertips – Wash hands with warm soapy water and dry before every glucose test. Lightly touch the lancing device against the site to be lanced. Press the release button. Gently squeeze the lanced site, and wipe away the first blood drop that appears. Squeeze your finger until a second small blood drop forms. Bring test strip to blood sample. The meter now display the blood drop and test strip symbols. This means your Liberty™ System is now ready for you to apply blood. Immediately bring the Liberty™ Test Strip to the blood sample. The test strip fills from the tip. Do not try to smear blood on the top surface.

The Liberty™ Test Strip acts like a sponge and draws the blood into the test strip through the sample area. The visual fill window of the Liberty™ Test Strip will now turn red. If the volume is enabled in SET Options, the meter will beep once when blood is applied to the Liberty™ Test Strip. On the display, blood drop symbols appear on the test strip symbol to indicate that blood is filling the Liberty™ Test Strip. The beep (if the volume is enabled in SET Options) or the moving dot bar indicates that you can remove your finger from the Liberty™ Test Strip.

As the meter is calculating your results, the 1-2-3 symbol and the graphing area will progressively appear until your results are displayed. Your test is completed when your blood glucose test result with time and date is shown on the display. If the volume is enabled in SET Options, you will hear a beep. Your test result is now stored in the memory.

Testing on Your Palm – Wash hands with warm soapy water and dry before every glucose test. Prepare the lancing device by replacing the gray lancing device cap with the clear cap. You may need to adjust the depth setting of the lancing device to produce a sufficient blood drop. To increase the blood flow in your palm, rub the area at the base of your thumb. Press the tip of the clear cap against your skin on the palm of your hand (at the base of the thumb). Hold the tip to your palm for a few seconds before pressing the release button. After lancing, hold the lancing device against your skin until a blood droplet forms. Make sure the blood droplet is large enough to completely fill the visual fill indicator window of the test strip.

IMPORTANT: When testing on the palm (at the base of the thumb), you may require 28 gauge Liberty™ Lancets in order to obtain enough blood to perform a test. Consult your physician for a recommendation.

5. Calibration:

Lot Specific adjusted calibration with pre-set test strip code number.

6. Quality Control:

Shake the control solution bottle. Discard the first drop of control solution and wipe of the bottle tip to ensure a good sample. Gently wet the sample area of the Liberty™ Test Strip with the control solution. The Liberty™ System will automatically detect if a test is performed with Liberty™ Control Solution. When the control solution is applied, the visual fill window on the Liberty™ Test Strip turns blue.

If the volume is enabled in DET Options, the meter will beep once when you should remove the control solution bottle from the tip of the Liberty™ Test Strip. On the Liberty™ Meter display, drop symbols appear on the test strip symbol to indicate that the control solution is filling the Liberty™ Test Strip. The result will appear on the display screen and, if the volume is enabled, your meter will beep once. The word “control” will also appear on the display screen. Compare the results of our control solution test to the range printed on the Liberty™ Test Strip vial label. Your control solution results should fall within this range. The control solution test result is stored in memory. Two levels of control material are available.

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

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.