

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY ONLY TEMPLATE**

**A. 510(k) Number:**

k130181

**B. Purpose for Submission:**

New device

**C. Measurand:**

Capillary and venous whole blood glucose

**D. Type of Test:**

Quantitative Amperometric Assay (Glucose Dehydrogenase (FAD) )

**E. Applicant:**

Infopia Co., Ltd

**F. Proprietary and Established Names:**

GluNEO™ Blood Glucose Monitoring System  
GluNEO™ Professional Blood Glucose Monitoring System

**G. Regulatory Information:**

<b>Product Code</b>	<b>Classification</b>	<b>Regulation Section</b>	<b>Panel</b>
LFR, NBW	Class II	21CFR 862.1345	Chemistry 75
JQP	Class II	21CFR 862. 2100	Chemistry 75
JJX	Class 1	21CFR 862.1660	Chemistry 75

**H. Intended Use:**

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

**GluNEO™ Blood Glucose Monitoring System**

The GluNEO™ Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh. The GluNEO™ Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The GluNEO™ Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The GluNEO™ Test Strips are for use with the GluNEO™ Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood. Fresh capillary whole blood samples may be drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh.

The GluNEO™ Control Solutions are for use with the GluNEO™ Meter and GluNEO™ Test Strips to check that the meter and test strips are working together properly and the test is performing correctly.

The GlucoDiary is a PC-based software intended for use in home to help people with diabetes in the review, analysis and evaluation of glucose test results for effective diabetes management. It is intended for use as an accessory to GluNEO™ Blood Glucose Monitoring System.

**GluNEO™ Professional Blood Glucose Monitoring System**

The GluNEO™ Professional Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in capillary whole blood from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh and in venous whole blood. The GluNEO™ Professional 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 diabetes control program. This system should only be used with auto-disabling, single-use lancing devices. The GluNEO™ Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

The GluNEO™ Professional Test Strips are for use with the GluNEO™ Professional Meter to quantitatively measure glucose (sugar) in venous whole blood samples and fresh capillary whole blood samples drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.

The GluNEO™ Professional Control Solutions are for use with the GluNEO™ Professional Meter and GluNEO™ Professional Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

The GlucoDiary is a PC-based software intended for use in professional settings to help healthcare professionals in the review, analysis and evaluation of their patients' glucose test results for effective diabetes management. It is intended for use as an accessory to GluNEO™ Professional Blood Glucose Monitoring System.

3. Special conditions for use statement(s):

- For in vitro diagnostic use only
- The single-patient use system is for single-patient use only and should not be shared
- The multiple-patient use system should only be used with single-use, auto-disabling lancing devices
- Not for neonatal use
- Do not use for diagnosis of or screening for diabetes mellitus
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients
- Alternative site testing (AST) should only be performed during periods of steady-state blood glucose conditions (when glucose is not changing rapidly)
- AST measurements should not be used for calibrating CGMeters
- AST measurements should not be used in insulin dose calculations

4. Special instrument requirements:

GluNEO™ Blood Glucose meter

GluNEO™ Professional Blood Glucose meter

**I. Device Description:**

The GluNEO™ and GluNEO™ Professional Blood Glucose Monitoring Systems are for single patient use and multiple patient use respectively. The systems consist of the GluNEO™ or GluNEO™ Professional meter, GluNEO or GluNEO Professional Test Strips and GluNEO or GluNEO Professional Control Solutions (Level 1, Level 2, and Level 3), a lancing device (disposable lancing device for GluNEO™ Professional).

The GluNEO™ Control Solutions are for use on the GluNEO™ and GluNEO™ Professional Blood Glucose Monitoring Systems to check that the meter and test strips are working together properly. The level 2 control solution is supplied with the start up kit. Other control solution levels can be purchased separately.

The GlucoDiary is optional data management software for use with GluNEO blood glucose meter, and it consists of a USB cable (or a RS-232 port cable) and a software program (provided in a CD or can be downloaded from the manufacturer website). The GlucoDiary allows the users to transfer blood glucose results from their glucose meter

to a computer maintain a history of their glucose test results, and convert them into graphs, charts and reports. The software does not recommend any medical treatment or medication dosage level.

**J. Substantial Equivalence Information:**

Predicate device name:

Ascensia® CONTOUR® Blood Glucose Monitoring System by Bayer HealthCare, LLC.

Predicate 510(k) number:

k062058

Comparison with predicate:

<b>Similarities and Differences in the meters and the strips</b>			
<b>Item</b>	<b>Candidate Device</b> GluNEO™ Glucose Monitoring System	<b>Candidate Device</b> GluNEO™ Professional Blood Glucose Monitoring System	<b>Predicate Device</b> Ascensia® CONTOUR® Blood Glucose Monitoring System (K062058)
Intended Use	The GluNEO™ Blood .  It is intended to be used for quantitative measurement of glucose in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same	Same
Assay Method	Electrochemical	Same	Same
Detection method	Amperometry	Same	Same
Enzyme	Glucose Dehydrogenase(FAD)	Same	Same
Reagent	FAD-Glucose Dehydrogenase: 11.6ug Mediator: Hexaammineruthenium Chloride 100ug Binder : 3.16ug Stabilizer : 47.7ug	FAD-Glucose Dehydrogenase: 11.6ug Mediator: Hexaammineruthenium Chloride 100ug Binder : 3.16ug Stabilizer : 47.7ug	FAD-Glucose Dehydrogenase: 6% Potassium Ferricyanide: 56% Non-reactive ingredients : 38%

Coding	Auto-coding	Same	Same
Sample type	fresh capillary whole blood from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh	capillary whole blood from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh and in venous whole blood.	Fresh capillary whole blood from the fingertip, palm, forearm, and in the case of neonates, the heel. Venous Whole Blood Neonatal Blood Arterial Blood
Operational Humidity range	10 ~ 90%	10 ~ 90%	10 ~ 93%
Operational Temperature range	10 ~ 40°C (50~104°F)	10 ~ 40°C (50~104°F)	5 ~ 45°C (40~113°F)
Test range	20 ~ 600 mg/dL	20 ~ 600 mg/dL	10 ~ 600 mg/dL
Hematocrit	25-65%	25 - 65%	0-70%
Read time	5 seconds	Same	Same
Sample volume	0.5uL	0.5 uL	0.6uL
Test Strip Storage Conditions	2 ~ 30°C (36~86°F)	2 ~ 30°C (36~86°F)	15 ~ 30°C (59~86°F)
Memory capacity	365 test results in the memory	365 test results in the memory	480 test results in the memory
Controls	3 levels	3 levels	Same

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

- ISO 15197:2003 In Vitro diagnostic test systems requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
- ISO 14971:2007 Medical devices- Application of risk management to medical devices.
- CLSI EP05-A2:2004 Evaluation of precision performance of quantitative measurement methods
- CLSI EP06-P2:2005 Evaluation of Linearity Quantitative Analytical Method
- CLSI EP07-A2 Interference Testing in clinical chemistry
- CLSI EP09-A2: 2002 Method comparison and bias estimating using patient samples.
- CEN13640:2002 Stability testing of in vitro diagnostic medical device

- EN 61326-1:2006 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
- EN 61326-2-6:2006 Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment
- IEC60068-2-64:2008 Environmental testing - Part 2: Test methods - Test Fh: Vibration, broad-band random (digital control) and guidance
- IEC61010-1:2001 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.
- IEC 61010-2-101:2002 Safety Requirements for electrical equipment for measurement, control and laboratory use Part 2-101: Particular requirements for In Vitro Diagnostic (IVD) Medical Equipment.

#### **L. Test Principle:**

The GluNEO™/ GluNEO™ Professional blood glucose test is based on the measurement of glucose concentration in human blood. The principle of the test is based on the reaction between glucose in the blood sample, FAD-Glucose Dehydrogenase and mediator. The resulting product generates current that is proportional to the glucose concentration in the sample. The test strip employs an electrochemical signal generating an electrical current that will stimulate a chemical reaction. The reaction is measured and displayed by the meter.

#### **M. Performance Characteristics (if/when applicable):**

All performance characteristics were conducted on GluNEO™ Blood Glucose Monitoring System and GluNEO™ test strips. Testing performed on the GluNEO™ Blood Glucose Monitoring System and GluNEO™ test strip to characterize performance of the GluNEO™ Professional Blood Glucose Monitoring System is adequate since both the GluNEO and GluNEO Professional meters and test strips are identical.

##### 1. Analytical performance:

###### *a. Precision/Reproducibility:*

Repeatability studies were performed with venous whole blood samples at five glucose concentrations (42, 81, 122, 203 and 335 mg/dL). Ten runs were performed on each sample with 10 replicates per strip lot resulting in a total of 100 replicates collected for 3 test strip lots on 4 meters and each glucose level tested. Results are summarized below:

Within-run precision for glucose (mg/dL)

Repeatability precision (whole blood)					
Strip Lot	Concentration (mg/dL) of glucose	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Lot.1	42	100	41.7	1.3	3.2
	81	100	79.4	1.8	2.3
	122	100	125.4	3.2	2.5
	203	100	205.9	3.4	1.6
	335	100	318.5	7.2	2.3
Lot.2	42	100	42.0	1.4	3.3
	81	100	78.9	1.9	2.5
	122	100	128.1	4.4	3.4
	203	100	207.5	2.8	1.3
	335	100	327.9	7.6	2.3
Lot.3	42	100	43.4	1.2	2.7
	81	100	79.0	1.9	2.4
	122	100	123.7	4.3	3.5
	203	100	206.0	3.2	1.5
	335	100	323.6	6.9	2.1

Intermediate precision was evaluated by measuring three different control solutions on 3 lots of test strips on 10 meters, 10 replicates per day for 20 days. The test strips were taken from the same vial for each sample.

Intermediate precision (control solution)					
Strip Lot	Sample level (mg/dL)	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Lot.1	49	200	50.8	1.5	2.9
	109	200	111.0	3.1	2.8
	305	200	310.9	4.0	1.3
Lot.2	49	200	48.8	1.5	3.2
	109	200	113.7	2.8	2.5
	305	200	313.8	9.5	3.0
Lot.3	49	200	51.6	1.7	3.3
	109	200	109.5	2.7	2.5
	305	200	308.8	7.2	2.3

*b. Linearity/assay reportable range:*

The sponsor performed linearity studies using adjusted venous blood samples with 14 different glucose concentrations ranging from 11.3, 22.4, 44.6, 53.6, 67.7, 87.8, 99.0, 183.5, 264.0, 354.5, 431.0, 528.5, 603.5 and 697.5 mg.dL for the GluNEO™ system.

For each concentration, 15 consecutive tests (with 5 measurements per lot) by GluNEO™ system and 2 measurements with the YSI 2300 Auto analyzer were performed respectively. The resulting data was compared and the linear regression analyses were as follows:

Strip Lot	Linear Regressions	Slope	Y-Intercept	R <sup>2</sup>
Lot. #1	y=1.0014-0.2767	1.0014	-0.2767	0.9999
Lot. #2	y=1.0050-1.0940	1.0050	-1.0940	0.9997
Lot. #3	y=1.0004-0.8686	1.0004	-0.8686	0.9999
Combined	y=1.0023-0.7464	1.0023	-0.7464	0.9998

The results of the study support the sponsor’s claimed glucose measurement range of 20 – 600 mg/dL.

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

Test Strip Stability: The sponsor provided a real-time and accelerated testing protocol and acceptance criteria to verify the closed- (shelf life) and open vial stability of the test strips. The stability protocols and acceptance criteria were reviewed and found to be acceptable. The sponsor claims a closed-vial (shelf life) of 20 months and open-vial stability of 3 months when stored at 36-86°F and 10%- 85% relative humidity. The labeling instructs the users not to freeze the test strips.

Traceability:

The GluNEO™ Blood Glucose system is traceable to the NIST SRM 917b reference material. The method comparison study was performed using the candidate device and YSI as the reference method. ( see section 2.a.)

Glucose control value assignment and stability:

The glucose controls are the same as the controls in k091157, except in product name. Value assignment and stability and stability for these controls can be found in k051285.

d. *Detection limit:*

See linearity study in Section M.1.b above.

e. *Analytical specificity:*

To assess potential interference the sponsor used venous whole blood samples

adjusted to three glucose concentrations of 55 mg/dL and 150 mg/dL and 300 mg/dL. Each of these samples was divided into a test pool and a control pool and each of the potential endogenous and exogenous interfering substances was added to the test pool. Each substance was tested at a minimum of two concentrations, normal/therapeutic and high/toxic concentrations. Each sample was analyzed in replicates of 5. The % difference between the test sample and the control sample was calculated. The sponsor defines no significant interference as  $\leq \pm 10$  mg/dL difference relative to the control sample with glucose concentrations  $< 75$  mg/dL and  $\leq \pm 10$  % with glucose concentrations  $\geq 75$  mg/dL. Results are presented in the table below:

Summary of concentration with no interference:

Potential interfering substance	Concentration at which no interference is observed (mg/dL)	Potential interfering substance	Concentration at which no interference is observed (mg/dL)
Acetaminophen	<u>20</u>	Creatinine	<u>5</u>
Bilirubin	<u>40</u>	Cholesterol	<u>500</u>
Gentistic acid	<u>1.8</u>	TG	<u>3000</u>
Levo-Dopa	<u>13</u>	Galactose	<u>50</u>
Methyl-Dopa	<u>1.5</u>	Xylose	<u>10</u>
Tolazamide	<u>5</u>	Maltose	<u>300</u>
Dopamine	<u>0.09</u>	Lactose	<u>100</u>
Ascorbic acid	<u>6</u>	Mannitol	<u>600</u>
Glutathione	<u>3</u>	Sorbitol	<u>70</u>
Ibuprofen	<u>50</u>	Ethanol	<u>400</u>
Salicylic acid	<u>60</u>	Hemoglobin	<u>200</u>
Tetracycline	<u>1.5</u>	Penicillin	<u>12</u>
Tolbutamide	<u>65</u>		
Urea	<u>260</u>		
Uric acid	<u>23</u>		

The labeling states the following :

-Acetaminophen, uric acid, ascorbic acid (vitamin C), and other reducing substances (when occurring in normal blood or normal therapeutic concentration) do not significantly affect results. However, abnormally high concentration in blood may cause inaccurately high results.

-Lipemic samples; cholesterol up to 500 mg/dL or triglyceride up to 3000 mg/dL do not significantly affect the results.

-Monosaccharide; abnormally high concentration of xylose in blood may cause inaccurately high results.

Substances that interfere:

For xylose, a dose response study was conducted on 5 xylose levels (0~20 mg/dL) at three blood glucose concentrations (<60, 150 and >300 mg/dL). It was determined that the highest level of xylose at which no significant interference occurs is 10 mg/dL.

f. Assay cut-off:

Not Applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

To assess system accuracy, results from the GluNEO™ Blood Glucose Monitoring System were compared to a reference method, YSI 2300. Fingerstick capillary samples were obtained from 100 participants with glucose concentrations ranging from 34-502 mg/dL obtained using the reference method. Trained healthcare professionals at each site collected finger stick blood from on each participant. In order to obtain sufficient samples in the lowest and highest concentration intervals, 10 samples were altered: 5 Samples that were < 50 mg/dL and 5 samples > 400 mg/dL were contrived samples and samples between 50 to 400mg/dL were natural samples. 6 meters with 3 test trip lots were used and the results of the GluNEO™ system relative to reference are summarized in the tables below:

System method comparison results for Glucose concentration <75 mg/dL

Strip Lot	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
Lot 1	11/16 (68.8%)	14/16 (87.5%)	16/16 (100.0%)
Lot 2	13/16 (81.3%)	15/16 (93.8%)	16/16 (100.0%)
Lot 3	12/16 (75.0%)	15/16 (93.8%)	16/16 (100.0%)
Combined	36/48 (75.0%)	44/48 (91.7%)	48/48 (100.0%)

System method comparison results for glucose concentration ≥75 mg/dL

Strip Lot	Within ±5 %	Within ±10 %	Within ±15 %	Within ±20 %
Lot 1	48/84 (57.1%)	77/84 (91.7%)	83/84 (98.8%)	84/84 (100.0%)
Lot 2	46/84 (54.8%)	72/84 (85.7%)	83/84 (98.0%)	84/84 (100.0%)
Lot 3	40/84 (47.6%)	71/84 (84.5%)	82/84 (97.6%)	84/84 (100.0%)
Combined	134/252 (53.2%)	220/252 (87.3%)	248/252 (98.4%)	252/252 (100.0%)

Linear regressions between GluNEO™ BGMS results and the YSI 2300 for the capillary whole blood samples:

Strip Lot	Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
Lot 1	$y = 0.9474x + 5.5971$	(0.923, 0.972)	(0.402, 10.792)	0.9841	100
Lot 2	$y = 0.9401 + 6.4385$	(0.919, 0.962)	(1.816, 11.061)	0.9872	100
Lot 3	$y = 0.9548 + 5.4634$	(0.929, 0.980)	(-0.041, 10.968)	0.9824	100
Combined	$y = 0.9474 + 5.8330$	(0.924, 0.971)	(0.726, 10.940)	0.9846	300

Alternate site testing:

To assess the performance of alternative site testing using GluNEO™ Blood Glucose Monitoring System by 3 health professionals, the sponsor performed a study in which the health professionals performed testing on the candidate device, using blood samples from 150 participants, collected at the following alternate sampling sites: dorsal hand, ventral palm, upper arm, forearm, calf and thigh. Results were analyzed by comparing blood glucose results obtained by the healthcare professional for GluNEO™ Blood Glucose Monitoring Systems against the YSI 2300 reference value obtained by trained technicians. The samples ranged from 67 - 569 mg/dL measured by YSI. The results are summarized in the tables below:

Clinician DORSAL HAND vs YSI 2300 Finger

System accuracy results for glucose concentration <75 mg/dL				
Within ± 5mg/dL		Within ± 10 mg/dL		Within ± 15mg/dL
1/4 (25%)		3/4 (75%)		4/4 (100%)
System accuracy results for glucose concentration ≥75 mg/dL				
Within ±5%	Within ±10%	Within ±15%	Within ±20%	
93/146 (64%)	136/146 (93%)	144/146 (99%)	146/146 (100%)	

Clinician DORSAL HAND vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
$y = 1.002x + 9.180$	(0.987, 1.017)	(5.047, 13.313)	0.9919	150

Clinician VENTRAL PALM vs YSI 2300Finger

System accuracy results for glucose concentration <75 mg/dL				
Within ± 5mg/dL		Within ± 10 mg/dL		Within ± 15mg/dL
2/4 (50%)		3/4 (75%)		4/4 (100%)
System accuracy results for glucose concentration ≥75 mg/dL				
Within ±5%	Within ±10%	Within ±15%	Within ±20%	
100/146 (68%)	133/146 (91%)	143/146 (98%)	146/146 (100%)	

Clinician VENTRAL PALM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
$y = 0.997x + 9.669$	(0.982, 1.011)	(5.642, 13.696)	0.9921	150

Clinician UPPER ARM vs YSI 2300Finger

System accuracy results for glucose concentration <75 mg/dL				
Within ± 5mg/dL		Within ± 10 mg/dL		Within ± 15mg/dL
2/4 (50%)		3/4 (75%)		4/4 (100%)
System accuracy results for glucose concentration ≥75 mg/dL				
Within ±5%	Within ±10%	Within ±15%	Within ±20%	
102/146 (70%)	134/146 (92%)	144/146 (99%)	146/146 (100%)	

Clinician UPPER ARM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
$y = 0.975x + 11.446$	(0.958, 0.992)	(6.671, 16.220)	0.9885	150

Clinician FOREARM vs YSI 2300 Finger

System accuracy results for glucose concentration <75 mg/dL				
Within ± 5mg/dL		Within ± 10 mg/dL		Within ± 15mg/dL
2/4 (50%)		3/4 (75%)		4/4 (100%)
System accuracy results for glucose concentration ≥75 mg/dL				
Within ±5%	Within ±10%	Within ±15%	Within ±20%	
99/146 (68%)	135/146 (92%)	145/146 (99%)	146/146 (100%)	

Clinician FORE ARM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
$y = 0.997x + 9.784$	(0.980, 1.014)	(4.991, 14.576)	0.9892	150

Clinician THIGH vs YSI 2300 Finger

System accuracy results for glucose concentration <75 mg/dL				
Within ± 5mg/dL		Within ± 10 mg/dL		Within ± 15mg/dL
2/4(50%)		4/4(100%)		4/4(100%)
System accuracy results for glucose concentration ≥75 mg/dL				
Within ±5%	Within ±10%	Within ±15%	Within ±20%	
102/146 (70%)	133/146 (91%)	143/146 (98%)	146/146 (100%)	

Clinician THIGH vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
$y = 0.998x + 1.748$	(0.980, 1.017)	(-3.374, 6.871)	0.9873	150

Clinician CALF vs YSI 2300 Finger

System accuracy results for glucose concentration <75 mg/dL				
Within ± 5mg/dL		Within ± 10 mg/dL		Within ± 15mg/dL
2/4(50%)		3/4(75%)		4/4(100%)
System accuracy results for glucose concentration ≥75 mg/dL				
Within ±5%	Within ±10%	Within ±15%	Within ±20%	
102/146 (70%)	135/146 (92%)	145/146 (99%)	146/146 (100%)	

Clinician CALF vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
$y = 1.001x + 9.419$	(0.990, 1.013)	(6.225, 12.613)	0.9952	150

b. Matrix comparison - Venous blood

To assess system accuracy with venous blood, results from the GluNEO™ Blood Glucose Monitoring System were compared to a reference method, YSI 2300.

Venous blood samples (EDTA anticoagulant collection tube) were obtained from 100 participants with glucose concentrations ranging from 34-502 mg/dL glucose obtained using the reference method. Trained healthcare professional at each site collected venous blood from each participant. In order to obtain sufficient samples in the lowest and highest concentration intervals, 10 samples were altered. 5 Samples that were < 50 mg/dL and 5 samples > 400 mg/dL were contrived samples and samples between 50 to 400mg/dL were natural samples. 6 meters with 3 test trip lots were used and the results of the GluNEO™ system relative to reference are summarized in the tables below:

System method comparison results for Glucose concentration <75 mg/dL

Strip Lot	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
Lot 1	13/16 (81.3%)	15/16 (93.8%)	16/16 (100.0%)
Lot 2	13/16 (81.3%)	15/16 (93.8%)	16/16 (100.0%)
Lot 3	14/16 (87.5%)	15/16 (93.8%)	16/16 (100.0%)
Combined	40/48 (83.3%)	45/48 (93.8%)	48/48 (100.0%)

System method comparison results for glucose concentration ≥75 mg/dL

Strip Lot	Within ±5 %	Within ±10 %	Within ±15 %	Within ±20 %
Lot 1	46/84 (54.8%)	78/84 (92.9%)	83/84 (98.8%)	84/84 (100.0%)
Lot 2	48/84 (57.1%)	78/84 (92.9%)	81/84 (96.4%)	84/84 (100.0%)
Lot 3	43/84 (51.2%)	76/84 (90.5%)	83/84 (98.8%)	84/84 (100.0%)
Combined	137/252 (54.4%)	232/252 (92.1%)	247/252 (98.0%)	252/252 (100.0%)

Linear regressions between GluNEO™ BGMS results and the YSI 2300 for the venous whole blood:

Strip Lot	Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
Lot 1	y = 0.9832x + 4.5231	(0.962, 1.004)	(0.107, 8.939)	0.9891	100
Lot 2	y = 0.9665x - 6.8845	(0.941, 0.992)	(1.451, 12.318)	0.9830	100
Lot 3	y = 0.9705x - 6.6268	(0.948, 0.993)	(1.720, 11.534)	0.9862	100
Combined	y = 0.9734x + 6.0115	(0.960, 0.987)	(3.198, 8.825)	0.9861	300

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):

To assess the performance of GluNEO™ Blood Glucose Monitoring System in the hands of the intended users, the sponsor performed a study with 150 lay user participants. Results were analyzed by comparing fingerstick blood glucose results from the GluNEO™ system obtained by the lay user against YSI. The samples ranged from 63 to 493 mg/dL as measured by the reference method. The results of the GluNEO™ system relative to reference are summarized in the tables below:

Lay users vs YSI 2300

System accuracy results for glucose concentration <75 mg/dL

Within ± 5mg/dL	Within ± 10 mg/dL	Within ± 15mg/dL
9/13 (69%)	12/13 (92 %)	13/13 (100 %)

System accuracy results for glucose concentration ≥75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
70/137(51%)	120/137(88%)	132/137(96%)	137/137(100%)

Linear regressions between GluNEO™ BGMS results and the YSI 2300 for the capillary whole blood samples:

User performance	Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
Lay user vs. YSI 2300	$y = 0.9961x - 1.1244$	(0.976, 1.016)	(-6.796, 4.548)	0.9848	150

Alternative site testing by user :

To assess the performance of alternative site testing using GluNEO™ Blood Glucose Monitoring System the in the hands of the intended users the sponsor performed a study with 150 lay user participants, who collected samples from each of dorsal hand, ventral palm, upper arm, forearm, calf and thigh samples. Results were analyzed by comparing blood glucose results obtained by the lay user for GluNEO™ Blood Glucose Monitoring Systems against the YSI 2300 reference value obtained by a trained technician. The samples ranged from 67-569 mg/dL measured by YSI. The results are summarized in the tables below:

GluNEO™ was assessed by comparing blood glucose results obtained by patients with those obtained using the YSI 2300 Auto analyzer, a laboratory instrument. 150 lay users who are fluent in English participated in the study.

Patient DORSAL HAND vs YSI 2300 Finger

System accuracy results for glucose concentration <75 mg/dL				
Within ± 5mg/dL		Within ± 10 mg/dL		Within ± 15mg/dL
1/4 (25%)		3/4 (75%)		4/4 (100%)
System accuracy results for glucose concentration ≥75 mg/dL				
Within ±5%	Within ±10%	Within ±15%	Within ±20%	
89/146 (61%)	130/146 (89%)	142/146 (97%)	146/146 (100%)	

Patient DORSAL HAND vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
y = 0.993x + 12.072	(0.977, 1.010)	(7.461, 16.683)	0.9897	150

Patient VENTRAL PALM vs YSI 2300 Finger

System accuracy results for glucose concentration <75 mg/dL				
Within ± 5mg/dL		Within ± 10 mg/dL		Within ± 15mg/dL
2/4 (50%)		3/4 (75%)		4/4 (100%)
System accuracy results for glucose concentration ≥75 mg/dL				
Within ±5%	Within ±10%	Within ±15%	Within ±20%	
104/146 (71%)	136/146 (93%)	143/146 (98%)	146/146 (100%)	

Patient VENTRAL PALM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
y = 0.981x + 10.596	(0.965, 0.997)	(6.102, 15.090)	0.9899	150

Patient UPPER ARM vs YSI 2300 Finger

System accuracy results for glucose concentration <75 mg/dL			
Within ± 5mg/dL	Within ± 10 mg/dL		Within ± 15mg/dL
2/4 (50%)	3/4 (75%)		4/4 (100%)
System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
102/146 (70%)	136/146 (93%)	143/146 (98%)	146/146 (100%)

Patient UPPER ARM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
y = 0.987x + 10.006	(0.972, 1.002)	(5.829, 14.182)	0.9913	150

Patient FOREARM vs YSI 2300 Finger

System accuracy results for glucose concentration <75 mg/dL			
Within ± 5mg/dL	Within ± 10 mg/dL		Within ± 15mg/dL
2/4 (50%)	4/4 (100%)		4/4 (100%)
System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
100/146 (68%)	130/146 (89%)	143/146 (98%)	146/146 (100%)

Patient FORE ARM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
y = 1.000x + 9.076	(0.983, 1.017)	(4.150, 14.003)	0.9887	150

Patient THIGH vs YSI 2300 Finger

System accuracy results for glucose concentration <75 mg/dL				
Within ± 5mg/dL		Within ± 10 mg/dL		Within ± 15mg/dL
2/4(50%)		3/4(75%)		4/4(100%)
System accuracy results for glucose concentration ≥75 mg/dL				
Within ±5%	Within ±10%	Within ±15%	Within ±20%	
93/146 (64%)	133/146 (91%)	144/146 (99%)	146/146 (100%)	

Patient THIGH vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
$y = 0.985x + 2.696$	(0.969, 1.002)	(-1.927, 7.319)	0.9894	150

Patient CALF vs YSI 2300 Finger

System accuracy results for glucose concentration <75 mg/dL				
Within ± 5mg/dL		Within ± 10 mg/dL		Within ± 15mg/dL
3/4(75%)		4/4(100%)		4/4(100%)
System accuracy results for glucose concentration ≥75 mg/dL				
Within ±5%	Within ±10%	Within ±15%	Within ±20%	
100/146 (68%)	134/146 (92%)	143/146 (98%)	146/146 (100%)	

Patient CALF vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
$y = 0.991x + 10.711$	(0.973, 1.009)	(5.575, 15.847)	0.9873	150

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Time of day	People without diabetes
Fasting and before meals	<100 mg/dL
1-2 hours after meals	<140 mg/dL

American Diabetes Association: *Diabetes Care Vol 36* (Supp. 1) January 2013, p S1-S100.

**N. Instrument Name:**

GluNEO™ Blood Glucose Monitoring System

GluNEO™ Professional Blood Glucose Meter

**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  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:

The glucose test is intended to be used with capillary whole blood from the finger, palm, thigh upper arm, forearm, thigh and calf, and also venous blood. The whole blood sample is applied directly to the test strip or using a lancing device but for both home and professional use no storing is required.

5. Calibration:

The system is designed for auto coding . The meter identifies the specified pre-coded test strip.

6. Quality Control:

Three levels of aqueous glucose control solutions are available with this system (Level 1, Level 2, and Level 3). Control solution Level 2 is provided with the kit. Recommendations on when to test the control materials are provided in the labeling. An acceptable range for each control level is printed on the test strip vial label.

**P. Other Supportive Device and Instrument Information:**

**1) Altitude study:**

To evaluate the effects of altitude on the GluNEO Glucose Monitoring System a study was performed to simulate pressure and oxygen changes from altitude differences. Altered (spiked and glycolyzed) venous blood samples from three donors were spiked to 9 glucose concentrations (41, 61, 115, 223, 260, 341, 390, 467 and 552 mg/dL). The blood samples were tested using one test strip lot (90 test strips) and 5 meters at the simulated altitude and the results compared to those obtained with the reference method (YSI). The results demonstrate acceptable bias to the reference to support the claims in the labeling that altitudes up to 10,000 feet have no significant effect on blood glucose measurements from the GluNEO™ Blood Glucose Monitoring System.

**2) Hematocrit Study:**

Venous samples were collected from the median cubital vein from 10 donors, centrifuged and divided it into plasma and red blood cell in order to adjust the Hematocrit to obtain the following 6 different percentages: 10, 25, 35, 42, 55, 65%. The concentration of glucose was adjusted in each hematocrit percentage listed above to the following 10 levels: 15, 41, 69, 115, 172, 254, 375, 443, 518, 650 mg/dL through either glycolysis or analytical spiking. Each sample was tested 15 times with the GluNEO™ System. The plasma serum glucose value of the each levels of sample was measured by YSI 2300 Auto analyzer and the hematocrit of the sample was measured by NOVA STAT profile and compared to mean of the YSI 2300 analyzer. The % biases relative to YSI were acceptable within the claimed hematocrit range of 25 - 65%.

**3) Sample volume study:**

A sample volume study was performed to verify the test strip minimum sample volume requirement and the test strip fill error requirement established for the

GluNEO™ BGMS. 5 glucose concentrations were tested ranging from 38~448 mg/dL, as determined by the YSI. Blood at each concentration was applied to strip at five target sample volumes of 0.3, 0.4, 0.5, 0.8 and 1.0uL. Appropriate sample volume was determined if the meter results matched the YSI results. The data shows that sample volume of  $\geq 0.5 \mu\text{L}$  is the smallest volume to produce acceptable results.

#### **4) Temperature and humidity study:**

Environmental testing was performed in a sealed environmental chamber that can be controlled for temperature and humidity. Prior to the test, 10 meters and 10 lots of the test strip were exposed to the following extreme conditions for 1h.

10°C, RH 10% (lowest temperature / lowest humidity)

40°C, RH 10% (highest temperature / lowest humidity)

10°C, RH 90% (lowest temperature / highest humidity)

40°C, RH 90% (highest temperature / highest humidity)

The results demonstrated that GluNEO™ BGMS be used at temperatures of 10~40°C(50~104 °F) and 10~90% relative humidity.

#### **5) Usability Study**

As part of the user performance study summarized in section M.2.a above, the participants were asked to complete a questionnaire to evaluate the ease of use of the device and the clarity of the English language labeling. Overall the users indicated that they could successfully perform the test and that the user manual was written clearly.

#### **6) Readability study**

Flesch-Kincaid readability assessment was conducted and the results showed that the labeling for the GluNEO™ Blood Glucose Monitoring Systems (the user manuals, the strip inserts and the control inserts of both systems(single patient use and multiple patient use system) have been evaluated for readability and the results shows that all the labeling were written at 8<sup>th</sup> grade level.

#### **7) EMC and electrical safety study**

EMC and electrical safety testing were evaluated and certified by the third party lab. The certificates were provided by the sponsor.

#### **8) Infection control studies**

The device systems are intended for single-patient use (GluNEO) and multiple-patient use (GluNEO Professional)

Cleaning and disinfection can be accomplished by wiping the meter and the reusable lancing device with Caviwipes™ (EPA Reg. No. 46781-8). The robustness study was conducted and the results demonstrated that there was no change in performance or in the external materials of the meter and the lancing device after 10,980 cleaning and disinfection cycles to simulate 3 years of use for both the single patient and professional users.. Each robustness cycle tested consisted of one pre-clean wipe and one disinfecting wipe.

**Virucidal Efficacy test:**

The device system is intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter and lancing device by an outside commercial testing laboratory 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 of the meter and lancing device after 10980 cleanings and 2 disinfection steps with the 1 wipe ( pre cleaning with one caviwipe towellet). The robustness studies were designed to simulate X years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

**9) GlucoDiary data storage and memory roll over study**

To assess the storage of the GlucoDiary device and the memory data rollover function, 365 data records were input into GlucoDiary device. The integrity of the stored data was confirmed by the data in GluNEO™ glucose meters with an accuracy of 100%. The study demonstrated that the new data will replace the existed data orderly after the memory area room is full.

**10) Usability of the GlucoDiary**

A human factor study was performed to verify that participants with average education and computer skills and no prior knowledge of the system can safely and accurately use the new device and the data transfer without direct instruction or training. A Study with 20 participants, downloading 30 data points was conducted and the results showed that these participants were able to transfer results from the meter to the GluNEO™ device via USB cable (or a RS-232 port cable) using a software program (provided in a CD or can be downloaded from the manufacturer website).

**11) Customer Care Service Center is available 9 am to 5 pm CST, Monday – Friday by calling 855-446-3246.**

**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.