

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

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

k132966

**B. Purpose for Submission:**

New device

**C. Measurand:**

Capillary whole blood glucose from the finger, ventral palm, dorsal hand, upper arm, forearm, calf and thigh, 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™ Lite Blood Glucose Monitoring System  
GluNEO™ Lite 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
JJX	Class I	21CFR 862.1660	Chemistry 75

**H. Intended Use:**

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

**GluNEO™ Lite Blood Glucose Monitoring System**

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

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

**GluNEO™ Lite Professional Blood Glucose Monitoring System**

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

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 Continuous Glucose Monitors (CGM)
- AST measurements should not be used in insulin dose calculations

4. Special instrument requirements:

GluNEO™ Lite Blood Glucose meter

GluNEO™ Lite Professional Blood Glucose meter

**I. Device Description:**

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

The GluNEO™ Lite Control Solutions are for use on the GluNEO™ Lite and GluNEO™ Lite 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 startup kit. Other control solution levels can be purchased separately. The GluNEO™ Lite Control Solutions are the same controls that were cleared in k091157 for the GluNEO Blood Glucose Monitoring Systems and have been renamed for this submission from GluNEO™ Control Solutions to GluNEO™ Lite Control Solutions.

**J. Substantial Equivalence Information:**

1. Predicate device name:  
Infopia Co., Ltd., GluNEO™ Professional Blood Glucose Monitoring System
2. Predicate 510(k) number:  
  
k130181
3. Comparison with predicate:

Blood Glucose Meter, Reagent Strips, and Controls

<b>Similarities</b>		
Item	<u>Candidate Device</u> GluNEO™ Lite and GluNEO™ Lite Professional Blood Glucose Monitoring System	<u>Predicate Device</u> GluNEO™ Professional Blood Glucose Monitoring System (k130181)
Intended Use	Same	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.
Assay Method	Same	Electrochemical
Detection Method	Same	Amperometry
Enzyme	Same	Glucose Dehydrogenase(FAD)
Reagent	Same	FAD-Glucose Dehydrogenase: 7.2% Mediator: Hexaammineruthenium Chloride 42.8% Binder: 2.2% Stabilizer: 47.8%
Test range	Same	20-600 mg/dL
Operational Humidity range	Same	10 ~ 90%
Operational Temperature range	Same	10 ~ 40°C (50~104°F)
Hematocrit	Same	25-65%
Read time	Same	5 seconds
Sample volume	Same	0.5uL
Test Strip Storage Conditions	Same	2 ~ 30°C (36~86°F)
Memory capacity	Same	365 test results in the memory

<b>Similarities</b>		
<b>Item</b>	<b>Candidate Device</b> GluNEO™ Lite and GluNEO™ Lite Professional Blood Glucose Monitoring System	<b>Predicate Device</b> GluNEO™ Professional Blood Glucose Monitoring System (k130181)
Coding	Same	Autocoding
Controls Levels and Ranges	Same	3 levels L1: low (~35-65 mg/dL) L2:medium (~80-120 mg/dL) L3:high(~255-345mg/dL)

**Blood Glucose Meter, Reagent Strips, and Controls**

<b>Differences</b>		
<b>Item</b>	<b>Device</b> GluNEO™ Lite and GluNEO™ Lite Professional Blood Glucose Monitoring System	<b>Predicate</b> GluNEO™ Professional Blood Glucose Monitoring System (k130181)
Meter Size H x W x T (mm)	81 x 52 x 16	96 x 56 x 24
Weight	43 grams	65 grams

**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 61326-2-6:2006Electrical 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™ Lite / GluNEO™ Lite 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™ Lite Blood Glucose Monitoring System and GluNEO™ Lite test strips. Testing performed on the GluNEO™ Lite Blood Glucose Monitoring System and GluNEO™ Lite test strip to characterize performance of the GluNEO™ Lite Professional Blood Glucose Monitoring System is adequate since both the GluNEO™ Lite and GluNEO™ Lite 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 (44, 83, 125, 208 and 332 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	44	100	43	1.4	3.3
	83	100	81	2.1	2.6
	125	100	126	3.2	2.5
	208	100	209	4.9	2.3
	332	100	335	8.5	2.5
Lot.2	44	100	44	1.4	3.3
	83	100	81	2.2	2.7
	125	100	128	3.3	2.6

	208	100	209	5.5	2.6
	332	100	329	8.2	2.5
Lot.3	44	100	44	1.4	3.3
	83	100	81	2.0	2.5
	125	100	126	3.5	2.8
	208	100	208	5.5	2.6
	332	100	332	8.4	2.5

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	45	200	52	1.6	3.1
	111	200	111	2.9	2.6
	307	200	312	6.2	2.0
Lot.2	45	200	49	1.5	3.1
	111	200	111	2.2	2.0
	307	200	312	9.2	2.9
Lot.3	45	200	52	1.7	3.3
	111	200	109	2.7	2.5
	307	200	309	7.2	2.3

*b. Linearity/assay reportable range:*

The sponsor performed linearity studies using adjusted venous blood samples with 14 different glucose concentrations to include the following: 19.8, 28.9, 47.1, 56.2, 65.3, 83.6, 92.7, 165.6, 238.4, 311.3, 384.3, 457.1, 529.9 and 602.8 mg/dL for the GluNEO™ Lite system.

For each concentration, 15 consecutive tests (with 5 measurements per lot) by GluNEO™ Lite 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=0.9804-0.9501	0.9804	-0.9501	0.9996
Lot. #2	y=0.9744-0.4684	0.9744	-0.4684	0.9998
Lot. #3	y=0.9853-0.9116	0.9853	-0.9116	0.9998
Combined	y=0.9804-0.7767	0.9804	-0.7767	0.9997

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):*

Traceability:

The GluNEO™ Lite 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.)

Test Strip Stability:

The sponsor provided a real-time and accelerated testing protocol and acceptance criteria to verify the closed- 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 2-30°C (36-86°F) and 10%- 85% relative humidity. The labeling instructs the users not to freeze the test strips.

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 for these controls can be found in k091157. The stability protocols and acceptance criteria were reviewed and found to be acceptable. The sponsor claims a closed-vial (shelf life) of 26 months and an open-vial stability of 3 months when stored at 8-30°C (46-86 °F).

d. *Detection limit:*

The reportable range is 20-600 mg/dL. 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 60 mg/dL and 115 mg/dL and 320 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  $\leq \pm 10\%$  difference relative to the control sample. Results are presented in the table below:

Summary of concentrations of each substance with no significant interference

Potential interfering substance	Highest concentration at which no interference is observed (mg/dL)	Potential interfering substance	Highest concentration at which no interference is observed (mg/dL)
Acetaminophen	20	Creatinine	5
Bilirubin	30	Cholesterol	500
Gentistic acid	1.8	Triglycerides	3000

Levo-Dopa	13	Galactose	50
Methyl-Dopa	1.5	Xylose	10
Tolazamide	5	Maltose	300
Dopamine	0.09	Lactose	100
Ascorbic acid	3.0	Mannitol	600
Glutathione	3	Sorbitol	70
Ibuprofen	37.5	Ethanol	400
Salicylic acid	60	Hemoglobin	200
Tetracycline	1.5	Penicillin	12
Tolbutamide	65	Uric acid	23
Urea	260		

The labeling states the following:

-Acetaminophen, uric acid, ascorbic acid (vitamin C), and other reducing substances (when occurring in normal or therapeutic concentrations) 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.

-Samples containing bilirubin up to 30.0 mg/dL, ascorbic acid up to 3.0 mg/dL and ibuprofen up to 37.5 mg/dL do not significantly affect results.

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

-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. The labeling contains the following warning: *Do not use during or soon after xylose absorption testing. Xylose will cause interference.*

f. *Assay cut-off:*

Not Applicable.

## 2. Comparison studies:

a. *Method comparison with predicate device:*

To assess system accuracy, results from the GluNEO™ Lite 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 50-400 mg/dL obtained using the reference method. Trained healthcare professionals at each site collected finger stick blood from each participant. In addition, in order to obtain sufficient samples in the lowest and highest concentration intervals, 10 samples were altered: 5 samples that were < 50mg/dL and 5 samples > 400 mg/dL were

contrived samples. Samples between 50 to 400 mg/dL were natural samples. The total sample glucose concentration range tested was from 29 to 582 mg/dL. Six meters with 3 test trip lots were used and the results of the GluNEO™ Lite 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	12/17 (70.6%)	15/17 (88.2%)	17/17 (100.0%)
Lot 2	12/17 (70.6%)	16/17 (94.1%)	17/17 (100.0%)
Lot 3	11/17 (64.7%)	17/17 (100.0%)	17/17 (100.0%)
Combined	36/48 (75.0%)	48/51 (94.1%)	51/51(100.0%)

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

Strip Lot	Within ±5 %	Within ±10 %	Within ±15 %	Within ±20 %
Lot 1	52/83 (62.7%)	76/83 (91.6%)	83/83 (100.0%)	83/83 (100.0%)
Lot 2	49/83 (59.0%)	72/83 (86.7%)	82/83 (98.8%)	83/83 (100.0%)
Lot 3	47/83 (56.6%)	73/83 (88.0%)	83/83 (100.0%)	83/83 (100.0%)
Combined	148/249 (59.4%)	222/249 (89.2%)	248/249 (99.6%)	249/249 (100.0%)

Linear regressions between GluNEO™ Lite 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 = 0.9918x + 1.0744	(0.962, 1.002)	(-3.236, 5.385)	0.9896	100
Lot 2	y = 0.9821x - 0.3199	(0.965, 0.999)	(-3.994, 3.354)	0.9925	100
Lot 3	y= 1.0019x + 1.9074	(0.985, 1.019)	(-5.530, 1.715)	0.9930	100
Combined	y= 0.9886x -0.3843	(0.978, 0.999)	(-2.610, 1.842)	0.9916	300

Alternative site testing:

To assess the performance of alternative site testing using GluNEO™ Lite Blood Glucose Monitoring System, the sponsor performed a study in which 3 health professionals performed testing on the candidate device, using blood samples from 150 participants, collected at the following alternative 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™ Lite Blood Glucose Monitoring Systems against the YSI 2300 reference value obtained by trained technicians. The samples ranged from 65 - 583 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
4/4 (100%)	4/4 (100%)		4/4 (100%)
System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
97/146 (66%)	131/146 (90%)	142/146 (97%)	146/146 (100%)

Clinician DORSAL HAND vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
y = 1.0058x + 3.685	(0.990, 1.021)	(-0.664, 8.054)	0.9910	150

Clinician 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
3/3 (100%)	3/3 (100%)		3/3 (100%)
System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
100/147 (68%)	132/147 (90%)	142/147 (97%)	147/147 (100%)

Clinician VENTRAL PALM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
y = 0.9929x + 4.284	(0.976, 1.009)	(-0.332, 8.899)	0.9896	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
3/4 (75%)	4/4 (100%)	4/4 (100%)

System accuracy results for glucose concentration $\geq 75$ mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
83/146 (57%)	125/146 (86%)	139/146 (95%)	146/146 (100%)

Clinician UPPER ARM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
$y = 0.9730x - 6.968$	(0.955, 0.991)	(1.829, 12.107)	0.9868	150

Clinician FOREARM vs YSI 2300 Finger

System accuracy results for glucose concentration $< 75$ mg/dL			
Within $\pm 5$ mg/dL	Within $\pm 10$ mg/dL	Within $\pm 15$ mg/dL	
0/3 (0%)	1/3 (33%)	3/3 (100%)	
System accuracy results for glucose concentration $\geq 75$ mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
101/147 (69%)	135/147 (92%)	142/147 (97%)	146/147 (99%)

Clinician FORE ARM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
$y = 0.9884x - 0.8611$	(0.971, 1.006)	(-5.699, 3.977)	0.9885	150

Clinician THIGH vs YSI 2300 Finger

System accuracy results for glucose concentration $< 75$ mg/dL			
Within $\pm 5$ mg/dL	Within $\pm 10$ mg/dL	Within $\pm 15$ mg/dL	
2/4 (50%)	2/4 (50%)	4/4 (100%)	
System accuracy results for glucose concentration $\geq 75$ mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
99/146 (68%)	123/146 (84%)	142/146 (97%)	146/146 (100%)

**Clinician THIGH vs YSI 2300 Finger**

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
$y = 0.9923x + 1.419$	(0.973, 1.011)	(-3.914, 6.752)	0.9863	150

**Clinician CALF vs YSI 2300Finger**

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%
101/146 (69%)	128/146 (88%)	140/146 (96%)	146/146 (100%)

**Clinician CALF vs YSI 2300 Finger**

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
$y = 1.0058x + 6.262$	(0.992,1.020)	(2.244, 10.279)	0.9924	150

*b. Matrix comparison -*

To assess matrix affects, capillary blood samples from one hundred participants were measured for blood glucose using a GluNEO™ Lite system. A healthcare professional collected the participants' capillary whole blood into the heparin tube and venous whole blood into EDTA and sodium heparin anticoagulant tubes. The venous whole blood with EDTA and sodium heparin were tested with the GluNEO™ lite system by the healthcare professional and the capillary blood sample with heparin anticoagulant was measured by the YSI 2300, which is not affected by EDTA and heparin anticoagulant. All of the samples tested were natural patient samples and were unaltered. Blood glucose concentrations measured on the reference method ranged from 54 to 390 mg/dL. Testing took place at three different clinical sites using six GluNEO™ Lite meters and one glucose strip lot. The data analysis and linear regression of the results are summarized below:

GluNeo™ Lite Venous whole blood (EDTA) vs. YSI 2300

System accuracy results for glucose concentration < 75 mg/dL		
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
9/12 (75.0%)	11/12 (91.7%)	12/12 (100%)

<b>System accuracy results for glucose concentration ≥ 75 mg/dL</b>			
Within ±5 %	Within ±10 %	Within ±15 %	Within ±20 %
61/88 (69.3%)	80/88 (90.9%)	87/88 (98.9%)	88/88 (100%)

GluNeo™ Lite Venous Whole Blood (EDTA) vs. YSI 2300

$$y = 0.9589x + 5.796, R^2 = 0.9856$$

GluNeo Lite Venous whole blood (Heparin) vs. YSI 2300

<b>System accuracy results for glucose concentration &lt; 75 mg/dL</b>		
Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
9/12 (75.0%)	11/12 (91.7%)	12/12 (100%)

<b>System accuracy results for glucose concentration ≥ 75 mg/dL</b>			
Within ±5 %	Within ±10 %	Within ±15 %	Within ±20 %
48/88 (54.5%)	74/88 (84.1%)	85/88 (96.6%)	88/88 (100%)

GluNeo™ Lite Venous whole blood (Heparin) vs. YSI 2300

$$y=0.9876x + 3.777, R^2 = 0.9821$$

The data support the use of the venous EDTA and heparin whole blood samples for glucose testing on the GluNEO Lite system in addition to fresh capillary whole blood samples.

3. Clinical studies:

- a. Clinical sensitivity: Not applicable
- b. Clinical specificity: Not applicable
- c. Other clinical supportive data (when a. and b. are not applicable):

User Performance Evaluation:

To assess the performance of GluNEO™ Lite Blood Glucose Monitoring System in the hands of the intended users, the sponsor performed a study with 150 lay user participants. The participants were provided with a GluNEO™ Lite Test kit system as draft labeled and packaged in English. Participants did not receive additional training, other instruction, assistance, or training material other than the English written package insert included with the

test kit. Results were analyzed by comparing finger stick blood glucose results from the GluNEO™ Lite system obtained by the lay user against YSI glucose performed by healthcare professionals. The samples ranged from 52 to 495 mg/dL as measured by the reference method. The results of the GluNEO™ Lite system relative to reference are summarized in the tables below:

GluNEO™ Lite Blood Glucose Monitoring System 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%
74/137(54%)	119/137(87%)	132/137(96%)	137/137(100%)

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

User Performance: Lay user vs YSI 2300

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
$y = 0.9970x - 1.2524$	(0.976, 1.019)	(-7.374, 4.870)	0.9827	150

Alternative site testing by lay user:

To assess the performance of alternative site testing using GluNEO™ Lite 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™ Lite Blood Glucose Monitoring Systems against the YSI 2300 reference value obtained by a trained technician. The samples ranged from 65-583 mg/dL measured by YSI. The results are summarized in the tables below:

GluNEO™ Lite 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
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%
92/146 (63%)	123/146 (84%)	143/146 (98%)	146/146 (100%)

Patient DORSAL HAND vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
y = 0.992x + 8.368	(0.975, 1.009)	(3.61, 13.12)	0.9891	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
2/3 (67%)	3/3 (100%)		3/3 (100%)
System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
100/147 (68%)	130/147 (88%)	144/147 (98%)	147/147 (100%)

Patient VENTRAL PALM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
y = 0.983x + 4.482	(0.966, 1.001)	(-0.332,9.298)	0.9885	150

Patient UPPER ARM vs YSI 2300Finger

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%
105/146 (72%)	130/146 (89%)	142/146 (97%)	146/146 (100%)

Patient UPPER ARM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
$y = 0.982x + 4.735$	(0.967, 0.997)	(0.449, 9.022)	0.9909	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	
2/3 (67%)	3/3 (100%)	3/3 (100%)	
System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
102/147 (69%)	125/147 (85%)	141/147 (96%)	147/147 (100%)

Patient FORE ARM vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
$y = 0.999x + 0.0575$	(0.981, 1.017)	(-5.167, 5.052)	0.9874	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	
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%
98/146 (67%)	124/146 (85%)	140/146 (96%)	146/146 (100%)

Patient THIGH vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
$y = 0.983x + 1.342$	(0.973, 1.011)	(-3.849, 6.830)	0.9863	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 $\geq 75$ mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
101/146 (69%)	128/146 (88%)	140/146 (96%)	146/146 (100%)

Patient CALF vs YSI 2300 Finger

Linear regression	95% CI Slope	95% CI Intercept	R <sup>2</sup>	N
$y = 0.991x + 5.692$	(0.974, 1.008)	(2.244, 10.279)	0.9924	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™ Lite Blood Glucose Meter

GluNEO™ Lite 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. Capillary whole blood is applied directly to the test strip from the puncture site. Venous blood is to be collected in a collection tube containing EDTA or heparin anticoagulant. The tube should be filled to the stated volume. The tube should be inverted several times immediately after drawing blood and before removing a sample from the tube for testing. A disposable transfer pipette is used to obtain a sample from the center of the collection tube. The sample should be used within 30 minutes of collection.

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 Not Covered In The "Performance Characteristics" Section above":**

**1) Altitude study:**

To evaluate the effects of altitude on the GluNEO Lite 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 (43, 66, 113, 222, 261, 344, 386, 435 and 548 mg/dL). The blood samples were tested using one test strip lot (90 test strips) and 5 meters at the simulated altitudes which ranged from 0 to 63000 feet (0

to 19215 m) 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 (3048 m) have no significant effect on blood glucose measurements from the GluNEO™ Lite Blood Glucose Monitoring System.

## **2) Hematocrit Study:**

Venous samples were collected from 10 donors, centrifuged and divided it into plasma and red blood cell in order to adjust the hematocrit to obtain the following 5 percentages: 20, 30, 42, 55, and 65%. The concentration of glucose was adjusted in each hematocrit percentage listed above to the following 10 levels: 30, 43, 70, 121, 182, 250, 375, 450, 495, and 556 mg/dL through either glycolysis or analytical spiking. Each sample was tested 15 times with the GluNEO™ Lite 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 20 - 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™ Lite BGMS. Five glucose concentrations were tested ranging from 43 to 460 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 3 lots of the test strips were exposed to the following extreme conditions for 1 hour:

- 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 can 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™ Lite 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 Lite) and multiple-patient use (GluNEO Lite Professional)

Robustness:

Cleaning and disinfection can be accomplished by wiping the meter 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 after 10,980 cleaning and disinfection cycles to simulate 3 years of use for both the single patient and multiple-patient use. Each robustness cycle tested consisted of one cleaning wipe and one disinfecting wipe.

Disinfection Efficacy test:

Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of duck hepatitis B virus (DHBV) with the chosen disinfectant, Caviwipes™ (EPA Registration #46781-8. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

## **9) Customer Care Service Center is available 24 hours a day, 7 days a week, and 365 days a year by calling 1-800-446-3246.**

**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.