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

A. 510(k) Number:
k061234

B. Purpose for Submission:
New device

C. Measurand:
Glucose, home glucose monitoring test

D. Type of Test:
Quantitative

E. Applicant:
GlucoPlus Inc.

F. Proprietary and Established Names:
GlucoPlus Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
   21 CFR §862.1345, Blood Glucose Test System, Over-the-Counter
   21 CFR §862.1660, Quality Control Material (assayed and unassayed)
2. Classification:
   Class II
   Class I, reserved
3. Product code:
   NBW, system, test, blood glucose, over the counter
   CGA, glucose oxidase, glucose
   JJX, single (specified) analyte controls (assayed and unassayed)
4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   The GlucoPlus is intended to measure glucose quantitatively in capillary whole blood taken from the fingerstick.

2. Indication(s) for use:
   The GlucoPlus Blood Glucose Test System is comprised of Control Solutions and Test Strip biosensors for use only with the GlucoPlus™ Blood Glucose Meter. It is for quantitative measurement of the concentration of glucose in capillary whole

blood taken from the fingerstick by people with diabetes at home and or by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

3. Special conditions for use statement(s):
   For use only with capillary whole blood taken from the finger
   This product is intended for over-the-counter and point-of-care use.

4. Special instrument requirements:
   GlucoPlus™ Blood Glucose Meter

I. Device Description:

The GlucoPlus Blood Glucose Monitoring System consists of a hand-held blood glucose meter, test strips, and control materials. The user enters a code for each lot of test strips manually; the meter software contains specific calibration information for each code. The meter is turned on by strip insertion; the user then supplies finger-tip blood or control solution to the strip and the meter starts the assay, which completes in 15 seconds. The meter's software converts the results read off the test strip into a plasma glucose concentration and displays the value on the meter's LCD screen.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   k964630

2. Predicate 510(k) number(s):
   Bayer Glucometer Elite Blood Glucose Meter
3. Comparison with predicate:

Similarities		
Item	**GlucoPlus**	**Ascensia ELITE**
Intended Use	Blood glucose monitoring for home and point-of-care	Same
System Components	Meter, calibration code strip, test strip, check strip, battery, control solutions	Same
Specimen	Capillary blood	Same, and cleared for arterial and neonatal specimens
Test Principle/ Enzyme/ Mediator	Electrochemical/ Glucose oxidase/ Potassium ferricyanide	Same/ same/ same
Calibration	Automatic (code strip)	Same
Stability	Closed strips and controls: 18 months Opened strips and controls: 3 months	Same

Operating Range	50 – 104^{o} F, relative humidity 20 - 80%,	Same
Differences		
Item	**GlucoPlus**	**Ascensia ELITE**
Sample Volume	1.5 ul	2.0 ul
Test Time	Within 15 seconds	30 seconds
Hematocrit Range	30 – 55%	20 – 60%
Test Range	40 – 600 mg/dL	20 – 600 mg/dL
Memory capacity	100 test results	20 test results

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

Area of Study	Reference Procedure	Procedure Title
Method Comparison/ Anticoagulant Studies	CLSI EP9-T	Method Comparisons and Bias Estimations Using Patient Samples.
Precision	CLSI EP5-T2	User Evaluation of Precision Performance of Clinical Chemistry Devices
Linearity	CLSI EP6-P2	Evaluation of the Linearity of Quantitative Methods
Interferences/ Cross-Reactivity	CLSI EP7-P	Interference Testing in Clinical Chemistry
Guidance	ISO 14971	Medical Devices – Application of risk management to medical devices
	ISO 15197	In vitro diagnostic test systems – requirements for blood glucose systems

L. Test Principle:

The test is based on the release of electrical potential after a two-step reaction where glucose and ferricyanide, in the presence of glucose oxidase, are converted into gluconolactone and ferrocyanide. Ferrocyanide, when electrical current is applied, becomes ferricyanide and releases electrons; the increase in current measured by the meter is proportional to the glucose concentration.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
      Precision testing in the manufacturer's facility was based on CLSI EP5-T2.

Within-run precision was established using whole blood samples from non-diabetic volunteers spiked or glycolyzed to yield 6 glucose concentrations ranging from 40 – 500 mg/dL. Results were compared to YSI values. One strip lot was tested. Within-run precision was tested on twenty replicates of each glucose level. Between-day precision was tested by testing two levels of control materials (approximately 100 and 300 mg/dL) tested four times a day over 20 days. Testing results are summarized in the tables below:

GlucoPlus: Within Run Precision

Glucose Conc. by YSI (mg/mL)	Mean Glucose by GlucoPlus (mg/dL) (n=20)	Standard Deviation	% CV
43.5	43.7	1.7	3.9
96.2	90.5	2.1	2.4
138	132.6	3.4	2.6
207	198.0	4.2	2.1
330	327.4	7.3	2.2
507	531.6	14.8	2.8

GlucoPlus: Between Day Precision

Control Solution	Mean (mg/dL) (n=80)	Std Dev	% CV
Level 1 (~100 mg/dL)	106	3.5	3.3
Level 2 (~300 mg/dL)	298	7.6	2.5

b. *Linearity/assay reportable range:*
Heparinized venous whole blood was spiked or glycolyzed to six concentrations between 44 mg/dL and 596 mg/dL (confirmed by YSI) then tested with the GlucoPlus and YSI. Six samples were tested for each method for each of three lots. Regression analysis showed a linear relationship between the GlucoPlus and the YSI method: $y = 0.972x + 2.27$, $R = 0.999$ (all lots combined).

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Control materials are traceable to YSI standards which are traceable to NIST SRM #917A (Clinical Dextrose). Real-time shelf life studies performed by the manufacturer indicate that control solutions and the unopened test strips have at least a 17 month life-span. Once the control solution or strip container is opened, they have been shown to be stable for 3 months.

d. *Detection limit:*
See linearity study above; the meter will report 'LO' for values less than 40 mg/dL.

e. Analytical specificity:

Assay interferents were tested in a dose-response manner following CLSI EP7-A guidelines. Aliquots of the blood were supplemented with glucose to a final concentration of 100 mg/dL and measured on a YSI analyzer. The interferent was prepared with an appropriate solvent, and spiked into the 100 mg/dL blood. A control pool was prepared by supplementing the blood with solvent minus the interferent. A series of four to five levels that included the maximum concentration of the substance that would be expected to be encountered in clinical practice were used for each interferent. The sponsor defined interference as the level of compound that caused ≥ ±10% difference between the interferent-spiked sample and a sample that did not contain interferent.

The table below shows the effect of common interferents at the upper end of normal or therapeutic levels on GlucoPlus test levels:

Interference at High-Normal or High Therapeutic Levels
GlucoPlus System

Interferent	Upper End Therapeutic or Normal Range (mg/dL)	Highest concentration tested with no interference (mg/dL)
Acetaminophen	2 mg/dL	2
Bilirubin	1.2 mg/dL	5
Cholesterol	300 mg/dL	500
Creatinine	1.5 mg/dL	30
Dopamine	N/A	10
Ephedrine	2 mg/dL	10
Ibuprofen	4.2 mg/dL	20
L-dopa	0.3~10 mg/dL	1 (positive bias)
Methyl dopa	0.5 mg/dL	1
Salicylate	30 mg/dL	30
Tetracycline	4 mg/dL	1 (positive bias)
Tolazamide	2.5 mg/dL	3
Tolbutamide	10 mg/dL	10
Triglycerides	190 mg/dL	300
Ascorbic acid	2 mg/dL	2.25
Uric acid	7.7 mg/dL	5 (positive bias)

These results suggest that L-dopa, tetracycline, and uric acid at physiologically relevant levels may cause blood samples to produce an artificially high value. Care should be exercised by people with gout,

undergoing dialysis, taking chemotherapy or radiation treatments, with Parkinson's disease, and those taking tetracycline or related antibiotics.

Hematocrit Effect:
The effect of sample hemoglobin variation on the GlucoPlus system was tested experimentally by preparing samples of known hematocrit (Hct) and spiking aliquots of these samples with three different levels of glucose. These samples were run on the GlucoPlus and YSI; there was less than an ± 14% bias across the claimed range of 30 ~ 55% Hct.

The meter was tested at different altitudes to assess the effect of low oxygen levels on meter performance. No effect on performance was found when the two control solutions were tested up to 8800 ft. above sea level. Higher elevations were not tested. The sponsor presented data that supported using the test system between 10°C to 40°C and 20 – 80% relative humidity.

f. Assay cut-off:
Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:
GlucoPlus Consumer Studies:
The consumer study was performed at one site with 120 lay-users and a technician. The lay-users ranged in age, education, and were about equally divided between males and females. The native language of most of the participants was English. Labeling materials were in English. Each participant performed their own fingerstick and tested their blood using the instructions in the User's Guide. A trained technician then performed another fingerstick and tested the blood on the same meter. Capillary blood was collected and measured on a YSI analyzer. Samples ranged from 57 – 481 mg/dL. Linear regression analysis of the data yielded the results below:

Lay users vs. YSI $y = 0.96x – 7.9$ $r = 0.985$
Technician vs. YSI $y = 0.95x – 6.6$ $r = 0.989$

GlucoPlus POC Studies:
The point-of-care (POC) study was performed at three sites on a total of 100 diabetic participants by one technician at each site. Each participant was tested twice – once each with two GlucoPlus meters - and once with the predicate meter. Linear regression analysis of the data yielded the results below:

GlucoPlus: POC Study Results

Location	n	GlucoPlus vs. Predicate	r	Sample Range (mg/dL)
Home Medical Dept.	58	y = 1.05x – 6.3	0.990	59 – 341
Metabolism Dept.	62	y = 1.03x – 6.1	0.986	56 – 392

Internal Dept.	80	y = 1.05x – 4.8	0.997	38 – 548
Total	200	y = 1.04x – 5.8	0.994	38 - 548

In this study, 28 of 28 samples that were <75 mg/dL were ±15 mg/dL and 170 of 172 samples that were ≥ 75 mg/dL were within ±20% of the reference value.

b. Matrix comparison:

This System is cleared for use with fingerstick capillary samples. The meter's software adjusts the whole-blood glucose reading to a plasma-equivalent reading.

3. Clinical studies:
   a. Clinical Sensitivity:
   See Method Comparison Studies section above.
   b. Clinical specificity:
   Not applicable.
   c. Other clinical supportive data (when a. and b. are not applicable):
   Not applicable.

4. Clinical cut-off:
   Not applicable.

5. Expected values/Reference range:
   The normal fasting adult glucose range for a non-diabetic is 70 – 105 mg/dL. One to two hours after a meal, normal blood glucose levels should be less than 140 mg/dL. A medical professional should determine the range that is appropriate for diabetes patients.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.