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

A. 510(k) Number:

k091168

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative enzymatic (glucose oxidase) electrochemical assay

E. Applicant:

Infopia Co., Ltd.

F. Proprietary and Established Names:

GlucoPhoneTM Blood Glucose Test System

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345, Glucose Test System

2. Classification:

   Class II

3. Product code:

   NBW - system, test, blood glucose, over the counter

   CGA - Glucose Oxidase, glucose

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   Glucophone™ Blood Glucose Testing System is for the quantitative measurement of the concentration of glucose in whole blood that can be taken from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh by diabetic patients or healthcare professionals in the home and in clinical setting. Glucophone™ Blood Glucose Testing System is for testing outside the body (in vitro diagnostic use only). GlucoPhone™ Blood glucose Testing system is for use with a cellular phone.
   GlucoPhone™ Blood glucose Testing system is not for neonatal use and not for diagnosis or screening of diabetes. Alternate site testing is for use during times of steady state.

2. Indication(s) for use:

   See intended use above.

3. Special conditions for use statement(s):

   Over the Counter (OTC)

   Not for diagnosis of or screening for diabetes mellitus

   Not for use on neonates

   Not for use in patients that are in shock, hypotensive individuals, hyperglycemic, or hyperosmolar state, with or without ketosis.

   Alternative site testing should be done during steady-state times when glucose is not changing rapidly, for example before meals.

4. Special instrument requirements:

   GlucoPhone Blood Glucose Meter and a Motorola Razor V3 series cell phone.

I. Device Description:

The GlucoPhoneTM Blood Glucose Test System consists of glucose meter, blood glucose test strips and three levels of control solution. The controls were previously cleared under submission k051285. The device only works when attached to a Motorola Razor V3 series cell phone. The device uses the cell phone's screen to display results and instructions.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Healthpia America Corp., GlucoPack™ Blood Glucose Monitoring System

2. Predicate 510(k) number(s):
   k052469

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection method	Amperometer	Amperometer
Enzyme	Glucose Oxidase	Glucose Oxidase
Test Range	20-600 mg/dL	20-600 mg/dL
HCT	30-55%	30-55%
operating temperature	10-40 °C	10-40 °C
operating humidity	10-90%	10-90%
strip stability (shelf lifetime)	2 years at 2-30°C	2 years at 2-30 °C
strip stability (use lifetime)	3 months at 2 ~ 30°C after opening	3 months at 2~30 °C after opening
Electrode	carbon electrode	carbon electrode

Differences		
Item	Device	Predicate
Test Time	5 seconds	9 seconds
Sample Volume	1.0uL	3uL
Mediator	Hexaammine-ruthenium Chloride	Potassium ferricyanide
Size:HxWxT (mm)	92x62x19	80.9x45x29.7
Weigh	45 g	93g
Results display	Display on cellular phone screen	Display on meter screen

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.

ISO 14971:2007 Medical devices- Application of risk management to medical devices.

IEC 60601-1-1:2005 Medical electrical equipment - Part 1: General requirements for basic

safety and essential performance

IEC 60601-1-2: 2004 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral Standard - Electromagnetic Compatibility - Requirements and Tests

CLSI EP09-A2: 2004 Method comparison and bias estimation using patient samples

CLSI EP06-P2:2005 Evaluation of the Linearity Quantitative Analytical Method

CLSI EP05-A2:2005 Evaluation of precision performance of quantitative measurement methods

CLSI EN7-A2:2005 Interference Testing in Clinical Chemistry

EN 13640:2002 Stability testing of in vitro diagnostic medical device

ISO 17511:2003 Measurement of quantities in biological samples-Metrological traceability of values assigned to calibrators and control materials

L. Test Principle:

The principle of the test relies on glucose in the blood sample to react with the electrodes in the test strip. The test strip employs an electrochemical signal generating an electrical current that will stimulate a chemical reaction. This reaction is measured by a glucose meter integrated in the battery pack of the cell phone and the results of the blood glucose are displayed on the cell phone.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Within run precision was performed using venous blood samples spiked with glucose to achieve higher glucose concentrations or allowed to age and undergo glycolysis to achieve lower blood concentrations. The samples tested ranged from 40 to 315 mg/dL. Ten GlucoPhone glucose meters were each used to test each sample 10 times (n=100 total). The mean values and coefficients of variation were calculated for each sample and are summarized below.

With-in precision					
	sample1	sample2	sample3	sample4	sample5
Mean (mg/dL)	40.0	78.9	127.0	203.9	315.3
SD (mg/dL)	1.4	2.0	2.8	5.9	11.6
%CV	3.5	2.5	2.2	2.9	3.7

Inter day precision was performed using three levels of GlucoPhone control solution. The controls ranged from 49 to 299 mg/dL. Ten GlucoPhone glucose meters were

used to test each sample once per day for ten days with each meter (n=100 for each sample). The mean values and coefficients of variation were calculated for each sample and are summarized below.

Inter day precision			
	sample1	sample2	sample3
Mean (mg/dL)	49	99	299
SD (mg/dL)	1.4	1.9	6.7
%CV	2.8	1.9	2.2

b. Linearity/assay reportable range:

The claimed reportable range for the Glucophone is from 20 mg/dL to 600 mg/dL. Linearity was evaluated by adjusting a blood sample to a high and a low concentration. The two concentrations were mixed to form 14 glucose concentrations between 10.8 to 599.2 mg/dL. These samples were then tested with the GlucoPhone and YSI analyzer. Each glucose level was measured 5 times by the GlucoPhone and in duplicate by YSI. Linear regression analysis was performed and calculated the following result: y=0.9965x + 0.2585, R2=1.00.

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

The glucose controls were previously cleared in 510(k) submission k051285. Shelf-life studies show that the unopened controls have a 26 month shelf life and are stable for 3 months after opening.

Stability testing demonstrated that the test strips were stable until the expiration date when stored as directed and for 3 months after the test strip vial was opened.

d. Detection limit:

The lower end of the measuring range is 20 mg/dL and was verified in the linearity study above.

e. Analytical specificity:

An interference study was conducted to determine the effect of common interfering substances based on the CLSI EP07-A guideline. Common interferences were evaluated by spiking venous blood with different glucose concentrations. Each of these concentrations was then spiked with the interfering compound at concentrations ranging from zero to the maximum concentration recommended in CLSI EP07-A to make the interference samples. Three levels of glucose concentrations (<60, 150, and 240 mg/dL) were tested. The % bias was calculated based on the differences between the spiked sample and the control sample. The results were all within ± 10 mg/dL of the reference sample for glucose values < 75 mg/dL and within ± 10% for glucose values > 75 mg/dL.

Based on the data, the sponsor claims no significant interference for the substances and concentrations listed in the table below:

Compound	High Concentration Tested
Acetaminophen	20 mg/dL
Bilirubin	40 mg/dL
Gentistic acid	50 mg/dL
Levo-Dopa	4 mg/dL
Methyl-Dopa	2.5 mg/dL
Tolazamide	5 mg/dL
Dopamine	13 mg/dL
Ascorbate	3 mg/dL
EDTA	640 mg/dL
Glutathione	1 mg/dL
Heparin	100 mg/dL
Ibuprofen	40 mg/dL
Salicylic acid	50 mg/dL
Tetracycline	0.4 mg/dL
Tolbutamide	100 mg/dL
Urea	500 mg/dL
Uric acid	20 mg/dL
Creatinine	30 mg/dL
Cholesterol	500 mg/dL
Triglycerides	3000 mg/dL
Galactose	50 mg/dL
Xylose	10 mg/dL
Maltose	300 mg/dL

The product 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. Lipidemic samples; cholesterol up to 500mg/dL or triglyceride up to 3000 mg/dL do not significantly affect the results.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

System accuracy was evaluated by comparing the fingertip results of 160 samples that spanned the claimed assay range to the results obtained on a Hitachi747. Samples ranged from 31 to 589 mg/dL. For levels less than 50 mg/dL and greater than 400 mg/dL, pooled anti-coagulated capillary whole blood specimens were allowed to glycolize or were spiked to the desired glucose levels. Regression analysis calculated a slope of 1.011, a y-intercept of 0.5426, and $R^2$was 0.988. The accuracy of the GlucoPhone vs. a laboratory reference analyzer in the format of ISO 15197 is given below.

System accuracy results for glucose concentration <75 mg/dL
GlucoPhone vs. Hitachi 747

Within ± 5mg/dL	Within ± 10 mg/dL	Within ± 15mg/dL
25/27 (93 %)	27/27 (100 %)	27/27 (100 %)

System accuracy results for glucose concentration ≥75 mg/dL
GlucoPhone vs. Hitachi 747

Within ±5%	Within ±10%	Within ±20%
88/133(66%)	124/133(93%)	133/133(100%)

b. Matrix comparison:

Not applicable

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):

Lay user studies:
The sponsor conducted a user study at three clinical sites (minimum of 50 users per site) where the lay-user and healthcare professional measured blood glucose levels from both fingerstick and alternative sites. English speaking participants, were instructed to read the manual and perform testing on their finger and then the alternative sites. The results were compared to results from a laboratory reference analyzer. At each clinical site, the lay-user tested themselves first by fingerstick then by using alternative sites with the GlucoPhone and recorded their results. A healthcare professional then measured blood samples from fingerstick and alternative sites with the GlucoPhone, and a venous sample with the reference method. The lay user then completed a questionnaire to cover

demographics and ease of use and understanding. Regression analysis of the participants' fingerstick value (ranged from 61 to 543 mg/dL) against a laboratory method (Hitachi 747) yielded the following results: y=0.9905X+4.3486, R^2=0.9933.

Patient AST site tested	N	Regression	R_2
DORSAL HAND vs Hitachi 747	150	y= 0.9895x + 3.482	0.9897
VENTRAL PALM vs Hitachi 747	150	y = 0.9874x + 1.704	0.9898
UPPER ARM vs Hitachi 747	150	y = 0..9813x + 1.870	0.9911
FORE ARM vs Hitachi 747	150	y = 0.9977x – 0.166	0.9885
THIGH vs Hitachi 747	150	y = 0.9885x + 1.584	0.9935
CALF vs Hitachi 747	150	y = 0.9902x + 1.111	0.9928

The accuracy of the GlucoPhone vs. a laboratory reference analyzer in the format of ISO 15197 is given below.

FINGER STICK (Patient) vs Hitachi 747

System accuracy results for glucose concentration <75 mg/dL			
Within ± 5mg/dL	Within ± 10 mg/dL	Within ± 15mg/dL	
11/11 (100%)	11/11 (100%)	11/11 (100%)	
System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
105/139 (76%)	135/139 (97%)	138/139 (99%)	139/139 (100%)

DORSAL HAND (Patient) vs Hitachi 747

System accuracy results for glucose concentration <75 mg/dL			
Within ± 5mg/dL	Within ± 10 mg/dL	Within ± 15mg/dL	
0/5 (0%)	5/5 (80%)	5/5 (100%)	
System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
110/145 (76%)	140/145 (97%)	145/145 (100%)	145/145 (100%)

VENTRAL PALM (Patient) vs Hitachi 747

System accuracy results for glucose concentration <75 mg/dL		
Within ± 5mg/dL	Within ± 10 mg/dL	Within ± 15mg/dL
3/5 (60%)	5/5 (100%)	5/5 (100%)

System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
99/145 (68%)	137/145 (94%)	145/145 (100%)	145/145 (100%)

UPPER ARM (Patient) vs Hitachi 747

System accuracy results for glucose concentration <75 mg/dL		
Within ± 5mg/dL	Within ± 10 mg/dL	Within ± 15mg/dL
4/5 (80%)	5/5 (100%)	5/5 (100%)

System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
100/145 (69%)	137/145 (94%)	144/145(99%)	145/145(100%)

FOREARM (Patient) vs Hitachi 747

System accuracy results for glucose concentration <75 mg/dL		
Within ± 5mg/dL	Within ± 10 mg/dL	Within ± 15mg/dL
3/5 (60%)	5/5 (100%)	5/5 (100%)

System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
99/145 (68%)	136/145 (94%)	143/145 (99%)	145/145 (100%)

THIGH (Patient) vs Hitachi 747

System accuracy results for glucose concentration <75 mg/dL		
Within ± 5mg/dL	Within ± 10 mg/dL	Within ± 15mg/dL
4/5(80%)	5/5(100%)	5/5(100%)

System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
115/145 (79%)	143/145 (99%)	145/145 (100%)	145/145 (100%)

CALF (Patient) vs Hitachi 747

System accuracy results for glucose concentration <75 mg/dL		
Within ± 5mg/dL	Within ± 10 mg/dL	Within ± 15mg/dL
3/5(60%)	5/5 (100%)	5/5 (100%)

System accuracy results for glucose concentration ≥75 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
111/145 (77%)	143/145 (99%)	145/145 (100%)	145/145 (100%)

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   The fasting blood glucose range for a person without diabetes is between 70mg/dL and 110 mg/dL.[1)] Two hours after meals, normal blood glucose levels should be less than 140mg/dL.[2)]

   1) Stedmans Medical Dictionary, 27th Edition, 1999, p755

   2) American Diabetes Association Clinical Practice Recommendations 2004, Diabetes Care Supplement 1, P.S9.

N. Instrument Name:

Infopia GlucoPhone™ Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and must be replaced with a new strip for additional readings.

2. Software:

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

   Yes ___X____ or No _____

   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__.

   All performance testing and software verification and validation was performed using the Motorola Razor V3 series cell phone.

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   This device is intended to be used with capillary whole blood from the finger, ventral palm, the dorsal hand, the forearm, the upper arm, the calf, and the thigh. The whole blood sample is applied directly to the test strip and there are no special handling or storage procedures.

5. Calibration:

   Strip lot-specific calibration is accomplished by embedding a calibration Code onto each GlucoPhone™ test strip, which then provides the Calibration Code information to the GlucoPhone™ meter when the strip is inserted.

6. Quality Control:

   The sponsor has three levels of control solutions available for this meter with all levels coming with the kit and also being available through the distributor. When a test strip is inserted into the meter, a control can be run. An acceptable range for each control level is printed on the test strip vial label. The user is instructed when to perform quality control testing and referred to a troubleshooting section at the end of the control test instructions of the owner's manual to identify possible reasons control results fall outside these ranges. The user is instructed to contact customer support if the QC fails a second time.

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

EMC testing was performed according to IEC/EN 60601-1

The sponsor evaluated the effects of hematocrit on whole blood samples adjusted to 5 hematocrit levels between 30% and55% at eight glucose concentrations between 30 mg/dL and 549 mg/dL. The results from each sample were compared to mean values from the same sample tested on the YSI analyzer. All of the samples tested had results within +/- 10 mg/dL of YSI results for values under 75 mg/dL. For samples over 75 mg/dL, 97% of the results were within +/- 10% of YSI results and 100% of the results were within +/-15% of YSI results. These results support the sponsor's claimed hematocrit range of 30% to 55%.

Altitude testing

Glucose values of venous blood with adjusted partial pressure of oxygen (pO2) were measured by GlucoPhone in an altitude chamber at sea level and 10,000 feet. These values were compared to YSI 2300 reference values. Samples with glucose levels of 68 mg/dL, 299 mg/dL, and 468 mg/dL showed differences of less than 3 mg/dL or 2% compared to YSI at sea level and at 10,000 feet. The sponsor stated in their labeling that the Glucophone can be used up to altitudes of 10,000 feet without affecting the results.

Temperature and humidity studies were performed using three glucose controls at low, middle, and high concentrations. To evaluate the effect of temperature on performance, five GlucoPhone meters and test strips were placed into a temperature programmable incubator and tested at 10°C, 23°C, and 40°C with constant humidity and allowed to equilibrate to the incubator temperature. The control results at 10°C and 40°C were compared to those at 23°C and all results were within ±5.7%, demonstrating that temperatures ranging from 10°C to 40°C did not affect the meter's performance. To evaluate the effect of humidity on performance, five glucose meters and test strips were tested at 10%, 37%, and 90% humidity with constant temperature and allowed to equilibrate to the incubator temperature and humidity. The control results at 10% and 90% humidity were compared to those at 37% humidity and all results were within ±3.2%, demonstrating that humidity ranging from 10% to 90% did not affect the meter's performance.

The sponsor assessed ease of understanding of the labeling by the lay users. Participants varied in age, education, country of origin and gender. The overall survey indicated that 100% of the users rated the ease of use of the instructions as either Very Good (89%) or Good (11%). The readability for the user manual, strip manual and control solution labeling are grades 6.7, 6.4 and 5.7, respectively.

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.