

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

A. 510(k) Number:

k113192

B. Purpose for Submission:

New device

C. Measurand:

Glucose in fresh capillary whole blood

D. Type of Test:

Quantitative amperometric whole blood glucose oxidase

E. Applicant:

Infopia Co., Ltd.

F. Proprietary and Established Names:

Healthpro™ Blood Glucose Monitoring System

G. Regulatory Information:

| Product Code | Classification | Regulation Section | Panel |
|--------------|-------------------|---|-------------------------|
| NBW | Class II | 21 CFR§ 862.1345, Glucose Test System | Clinical Chemistry (75) |
| LFR | Class II | 21 CFR§ 862.1345, Glucose Test System | Clinical Chemistry (75) |
| JJX | Class I, reserved | 21 CFR § 862.1660, Quality control material | Clinical Chemistry (75) |

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

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

The Healthpro™ Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Healthpro™ 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 Healthpro™ test strips are for use with the Healthpro™ meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.

The Healthpro™ control solutions are for use with the Healthpro™ meter and test strips to check that the meter and test strips are working together properly and that the test as a quality control checks to verify the accuracy of blood glucose test results.

3. Special conditions for use statement(s):

For Over-the-Counter use

Not for neonatal use

Not for screening or diagnosis of diabetes mellitus

Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients

Alternative site testing (AST) can be used only during steady-state blood glucose conditions.

AST should not be used to calibrate continuous glucose monitors (CGMs) nor for use in insulin dose calculations.

AST testing should only be done during steady-state times (when glucose is not changing rapidly).

Single-patient use only system; should not be shared

4. Special instrument requirements:

The Healthpro™ Blood Glucose Meter

I. Device Description:

The Healthpro™ Blood Glucose Monitoring System consists of the meter, test strips and control solutions (Levels 1, 2, and 3), a lancing device and sterile lancets. The blood glucose

test system is an in vitro diagnostic device designed for measuring the concentration of glucose in whole blood sample by means of an electrical current produced in the test strip and sent to the meter for measurement.

J. Substantial Equivalence Information:

1. Predicate device name(s):

GLUCOLAB Auto-coding Blood Glucose Monitoring System

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

k091157

3. Comparison with predicate:

| Similarities | | |
|--------------------|--|--|
| Item | Healthpro™ Blood Glucose Monitoring System (Candidate Device) | GLUCOLAB Auto-coding (Predicate Device, k091157) |
| Indication For Use | <p>The Healthpro™ Blood Glucose Monitoring System is intended for used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.</p> <p>The Healthpro™ Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.</p> <p>The Healthpro™ test strips are for use with the Healthpro™ meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.</p> | Same |
| Assay Method | Electrochemical | Same |
| Detection method | Amperometry | Same |

| | | |
|-----------------------|--|------|
| Enzyme | Glucose Oxidase | Same |
| Measuring Range | 20 – 600 mg/dL | Same |
| Test Time | 5 seconds. Automatic measurement starts after complete fill of test strip. | Same |
| Memory capacity | 365 test results in the memory 7, 14, 21-day average | Same |
| Power source | 3V Li battery (CR2032x2ea) | Same |
| Operating temperature | 10 - 40 °C (50 - 104 °F) | Same |
| Operating humidity | 10 - 90 % | Same |
| Data transfer | Diabetes management software Via interface cable | Same |
| Display Type | LCD | Same |
| Sample | Fresh capillary whole blood | Same |
| Test time | 5 sec | Same |
| Electrode | Carbon electrode | Same |
| Storage Conditions | Store 36 - 86 °F (2 - 30 °C) and no direct sunlight. Do not Freeze | Same |
| Test Strip Dimension | 33 mm x 6 mm x 0.6mm | Same |

| Differences | | |
|----------------------|---|---|
| Item | Healthpro™ Blood Glucose Monitoring System (Candidate Device) | GLUCOLAB Auto-coding (Predicate Device, k091157) |
| Battery Life | IGM-0028A: Running 5,000 Tests IGM-0028B(Back Light LCD): Running 1,000 Tests | Running 5,000 Tests N/A |
| SIZE (L x W x H) | 88.4 x 50.3 x 18.5 (mm) | 85 x 50 x 20 (mm) |
| Weight | 46 ± 1g (including batteries) | 49g (including batteries) |
| Sample Volume | 0.5 uL | 1.0 uL |
| Reagent | Glucose Oxidase: 12ug Mediator (Hexaammineruthenium): 100ug Binder:3.16 ug Stabilizer: 47.7 ug | Glucose Oxidase: 21ug Mediator (Hexaammineruthenium): 139ug Binder:86 ug Stabilizer: 57 ug |
| Hematocrit range (%) | 20-60% | 30-55% |

| Control Solutions | | |
|---------------------|--|---|
| Proprietary | Healthpro™ control solutions (Candidate Device) | GLUCOLAB Auto-coding (Predicate Device, k091157) |
| Indication for Use | The Healthpro™ control solutions are for use with the Healthpro™ meter and test strips to check that the meter and test strips are working together properly and that the test as a quality control checks to verify the accuracy of blood glucose test results. | Same |
| Analyte | Glucose | Same |
| Number of levels | 3 levels (levels 1, 2 and 3) | Same |
| Compositions | Level 1: 0.04 wt% glucose 99.96 wt% non-reactive ingredients | Same |
| | Level 2: 0.12 wt% glucose 99.88 wt% non-reactive ingredients | Same |
| | Level 3: 0.20 wt% glucose 99.80 wt% non-reactive ingredients | Same |
| Container | Bottle | Same |
| Storage temperature | 8 - 30 °C (46 - 86 °F) | Same |
| Shelf Life Time | 24 months | Same |
| Use Life Time | 3 months after first opening | Same |

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

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

ISO 14791: Medical Devices – Application of risk management to medical devices.

CLSI Guideline, EP05-A2: Evaluation of precision performance of quantitative measurement methods; Approved Guideline.

CLSI Guideline, EP6-A: Evaluation of the Linearity of Quantitative Analytical Methods; Proposed Guideline.

CLSI Guideline, EP7-A2 Interference Testing in Clinical Chemistry; Approved Guideline.

CLSI Guideline, EP09-A2: method comparison and bias estimation using patient samples; Approved guidelines.

CEN 13640: Stability testing of in vitro diagnostic medical device.

CISPR11: Limits and measure of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency.

EN61326: Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: general requirements

EN61326: Electrical equipment fro measurement, control and laboratory use – EMC requirements. Particular requirements. In vitro diagnostic equipment.

IEC 60068-2-64: Environmental testing - Part 2: Test methods – Test Fh: Vibration, broad – band random (digital control) and guidance.

IEC 61010-1: Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General Requirements.

IEC 61010-2: 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 Healthpro™ blood glucose test is based on the measurement of glucose concentration in human blood. This enzyme assay, with a redox chemical “mediator” reaction, is used to generate an electrical current proportional to the glucose concentration in the blood sample. The system is designed as an amperometric measurement device using current generated from the redox reaction as the measurable response.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Within run precision was performed using five venous blood samples spiked with glucose to achieve higher glucose concentration or allowed to age and undergo glycolysis to achieve lower blood concentration. The samples tested ranged from 43 to 332 mg/dL. Each sample was tested 10 times on three test strip lots, using 10 meters per test strip lots for a n = 100 per test strip lot. The mean values and coefficients of variation were calculated for each sample and are summarized below.

| Within-day precision (whole blood) | | | | | |
|------------------------------------|-------------------------------|-----|--------------|------------|--------|
| Lot # | Glucose Concentration (mg/dL) | n | Mean (mg/dL) | SD (mg/dL) | CV (%) |
| 1 | 43 | 100 | 40.9 | 1.3 | 3.1 |
| | 80 | 100 | 78.4 | 1.8 | 2.3 |

| | | | | | |
|---|-----|-----|-------|-----|-----|
| | 121 | 100 | 124.3 | 3.1 | 2.5 |
| | 201 | 100 | 205.0 | 3.3 | 1.6 |
| | 332 | 100 | 317.8 | 7.4 | 2.3 |
| 2 | 43 | 100 | 41.1 | 1.4 | 3.4 |
| | 80 | 100 | 77.9 | 1.9 | 2.5 |
| | 121 | 100 | 127.2 | 4.4 | 3.5 |
| | 201 | 100 | 206.6 | 2.8 | 1.3 |
| | 332 | 100 | 326.8 | 7.3 | 2.2 |
| 3 | 43 | 100 | 42.4 | 1.2 | 2.8 |
| | 80 | 100 | 78.0 | 1.9 | 2.5 |
| | 121 | 100 | 122.6 | 4.3 | 3.5 |
| | 201 | 100 | 204.9 | 3.2 | 1.5 |
| | 332 | 100 | 322.7 | 6.7 | 2.1 |

The intermediate precision evaluation was performed using three levels of control solutions with glucose concentrations ranging from 30 to 420 mg/dL on three lots of test strips, 10 replicates per day for 20 days. The glucose concentration of each sample was determined using the blood-glucose monitoring system. The mean values and coefficients of variation were calculated for each sample and are summarized below.

| Day-to-day precision (control materials) | | | | | |
|--|-----|---------------------------|--------------|------------|--------|
| Lot # | N | YSI Concentration (mg/dL) | Mean (mg/dL) | SD (mg/dL) | CV (%) |
| 1 | 200 | 52 | 52.9 | 1.4 | 2.7 |
| | 200 | 110 | 110.2 | 3.2 | 2.9 |
| | 200 | 308 | 310.2 | 3.9 | 1.3 |
| 2 | 200 | 52 | 50.9 | 1.5 | 2.9 |
| | 200 | 110 | 112.9 | 2.7 | 2.4 |
| | 200 | 308 | 313.4 | 9.6 | 3.1 |
| 3 | 200 | 52 | 53.6 | 1.7 | 3.2 |
| | 200 | 110 | 108.7 | 2.8 | 2.6 |
| | 200 | 308 | 308.1 | 7.5 | 2.4 |

b. Linearity/assay reportable range:

A linearity study was performed using fourteen different levels of venous whole blood samples supplemented with a glucose stock solution to cover the claimed measuring range from 20.0 to 600.0 mg/dL. Five measurements were taken from each glucose level and measured using the Healthpro system. First order regression analysis resulted in the equation $y = 0.9925x + 1.4254$ with an $R^2 = 0.9996$. The claimed measuring range is 20 to 600 mg/dL based on the linearity data.

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

Traceability

The glucose control standards are traceable to a NIST glucose standard and are prepared at three concentrations (Level 1 = 50 mg/dL, Level 2 = 110 mg/dL and Level 3 = 300 mg/dL). The reference instrument used is the YSI 2300 Glucose analyzer and is calibrated by YSI 2747 Glucose Standard which is a NIST traceable glucose standard.

Stability

Accelerated stability study was conducted to assess the shelf-life and open-vial stability of the control solutions and test strips. Real-time stability studies are still ongoing. Stability studies protocol and acceptance criteria were provided and found to be adequate.

Unopened control solutions have a 24 month shelf life and are stable for 3 months after first use when stored at 2 - 30 °C (35.6 - 86 °F).

Unopened test strips have a 24 month shelf-life and are stable for 3 months after first use when stored at 2 - 30 °C (35.6 - 86 °F).

Expected values

The controls are prepared at three target concentrations gravimetrically and the glucose concentrations are verified with the YSI reference method. The expected values are verified for each new lot of strips.

d. Detection limit:

See linearity study above in section 1.b.

e. Analytical specificity:

Interference study was designed according to CLSI EP7-A2 guideline. 26 common endogenous and exogenous interfering substances were evaluated by spiking venous blood to three levels of glucose concentrations (60, 150 and 300 mg/dL). The glucose samples were then spiked with the potentially interfering compounds (6 concentration including normal or therapeutic levels and high of toxic levels). Five meters were used for this study. Each sample is tested in replicates of five and a total of 1950 test

strips were used. Bias was calculated as the mean percent difference in glucose reading between the test and control concentration groups. The sponsor claims no significant interference if bias between the tested and the control sample is <10% difference. A summary of the concentrations of the potential interfering substances tested is summarized in the table below:

| Interfering Substances | Maximum Concentration tested (mg/dL) |
|------------------------|--------------------------------------|
| Acetaminophen | 20 |
| Ascorbate | 6 |
| Ascorbic Acid | 6 |
| Cholesterol | 500 |
| Conjugated-Bilirubin | 40 |
| Creatinine | 5 |
| Dopamine | 0.09 |
| Ethanol | 400 |
| Galactose | 50 |
| Gentistic | 1.8 |
| Glutathione | 3 |
| Hemoglobin | 200 |
| Ibuprofen | 50 |
| Lactose | 100 |
| L-Dopa (Levo-Dopa) | 13 |
| Maltose | 300 |
| Mannitol | 600 |
| Methyl Dopa | 1.5 |
| Salicylic Acid | 60 |
| Sorbitol | 70 |
| Tetracycline | 1.5 |
| Tolazamide | 5 |
| Tolbutamide | 65 |
| Triglycerides | 3000 |
| Unconjugated-Bilirubin | 40 |
| Uric Acid | 23 |
| Urea | 260 |
| Xylose | 10 |

Based on the study data, all the substances and levels tested above have < 10% bias.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

The accuracy of the Healthpro™ Blood Glucose Monitoring System was assessed by comparing blood glucose results obtained from patients with those obtained using the YSI 2300, a laboratory instrument. A total of 160 samples were tested using 6 meters and a total of 960 Healthpro™ test strips.

Only unaltered capillary blood samples are used for glucose concentrations of 50 mg/dL to 400mg/dL. If necessary to obtain sufficient samples in the lowest and highest concentration intervals, glucose concentrations may be adjusted. For preparing some samples in very low glucose (< 50mg/dL) or very high glucose range (>400mg/dL), blood was collected in capillary heparin tubes and then either incubated to allow glucose to hydrolyse or supplemented with glucose. Capillary whole blood glucose was then measured by the Healthpro™ Blood Glucose Monitoring System. The capillary whole blood was then centrifuged, and the plasma glucose was measured by the YSI 2300 Auto analyzer. The data is summarized below:

System Accuracy Results for Glucose concentration <75mg/dL

| Strip Lot | Within ± 5mg/dL | Within ± 10 mg/dL | Within ±15 mg/dL |
|-----------|-----------------|-------------------|------------------|
| 1 | 18/27 (70%) | 26/27 (96%) | 27/27 (100%) |
| 2 | 17/27 (63%) | 27/27 (100%) | 27/27 (100%) |
| 3 | 19/27 (70%) | 25/27 (93%) | 27/27 (100%) |
| Combined | 54/81 (67%) | 78/81 (96%) | 81/81 (100%) |

System Accuracy Results for Glucose concentration ≥75mg/dL

| Strip Lot | Within ± 5% | Within ± 10% | Within ± 15% | Within ± 20% |
|-----------|---------------|---------------|---------------|----------------|
| 1 | 90/133 (68%) | 120/133 (91%) | 132/133 (99%) | 133/133 (100%) |
| 2 | 73/ 133 (55%) | 114/133 (86%) | 128/133 (96%) | 133/133 (100%) |
| 3 | 79/133 (59%) | 111/133 (83%) | 130/133 (98%) | 132/133 (99%) |
| Combined | 242/399 (61%) | 345/399 (86%) | 390/399 (98%) | 398/399 (99%) |

Regression between Healthpro™ BGMS results and the YSI 2300 for the capillary blood samples:

| Strip Lot | Linear Regressions | 95% CI Slope | 95%CI Intercept | R ² | N |
|-----------|--------------------|----------------|-----------------|----------------|-----|
| 1 | Y=0.9577x + 4.4167 | 0.946 to 0.970 | 1.910 to 6.923 | 0.9939 | 160 |
| 2 | Y=0.9747x + 4.1049 | 0.960 to 0.989 | 1.083 to 7.122 | 0.9914 | 160 |
| 3 | Y=0.9706x + 4.9351 | 0.956 to 0.985 | 1.768 to 8.103 | 0.9905 | 160 |
| Combined | Y=0.9676x + 4.4849 | 0.954 to 0.985 | 1.587 to 7.383 | 0.9917 | 480 |

b. *Matrix comparison:*

Not applicable. Capillary whole blood is the only indicated matrix.

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

One hundred and fifty (150) lay users fluent in English participated in the study. Three clinical sites were used with fifty lay users per site. Each participant was given a readability questionnaire, the instructions and the Healthpro™ system. Layperson's hematocrit value was measured with NOVA system. Each participant obtained samples from their fingertip, dorsal hand, ventral palm, upper arm, forearm, calf and thigh and tested these samples on the Healthpro™ Blood Glucose Meter using only the instructions in the user's manual and test strip insert. A healthcare professional collected blood from fingertip, dorsal hand, ventral palm, upper arm, forearm, calf, and thigh and tested the sample using the same meter. Capillary blood was also collected by healthcare professional and measured on an YSI-2300 Glucose Analyzer. Linear regression results from lay users and professionals are presented below.

| Test Item | Health Care Professional vs YSI 2300 | | | Layperson vs YSI 2300 | | |
|-------------------------|--------------------------------------|-------------------|------------------|-----------------------|-------------------|------------------|
| Slope | *0.9883 | | | *0.9786 | | |
| y-intercept | 0.5067 mg/dL | | | 0.8057 mg/dL | | |
| Correlation coefficient | 0.9854 | | | 0.9821 | | |
| No. of samples | 150 | | | 150 | | |
| Range tested | 65-490 mg/dL | | | 65-490 mg/dL | | |
| <75 mg/dL | Within ± 5mg/dL | Within ± 10 mg/dL | Within ± 15mg/dL | Within ± 5mg/dL | Within ± 10 mg/dL | Within ± 15mg/dL |
| | 9/12 (75 %) | 12/12 (100 %) | 12/12 (100 %) | 9/12 (75 %) | 12/12 (100 %) | 12/12 (100 %) |

| | | | | | | | | |
|-----------|------------------|-------------------|-------------------|--------------------|------------------|-------------------|--------------------|--------------------|
| ≥75 mg/dL | Within ±5% | Within ±10% | Within ±15% | Within ±20% | Within ±5% | Within ±10% | Within ±15% | Within ±20% |
| | 92/138 (67 %) | 128/138 (93 %) | 136/138 (99 %) | 138/138 (100 %) | 77/138 (56 %) | 128/138 (93 %) | 138/138 (100 %) | 138/138 (100 %) |

Results at each alternative site (dorsal hand, ventral palm, upper arm, forearm, calf, and thigh) are presented below:

Table 1. Data analysis at DORSAL HAND

Patient DORSAL HAND vs YSI 2300

| | | |
|---|-------------------|------------------|
| System accuracy results for glucose concentration <75 mg/dL | | |
| Within ± 5mg/dL | Within ± 10 mg/dL | Within ± 15mg/dL |
| 0/4 (0%) | 4/4 (100%) | 4/4 (100%) |

| | | | |
|---|------------------|-------------------|-------------------|
| System accuracy results for glucose concentration ≥75 mg/dL | | | |
| Within ±5% | Within ±10% | Within ±15% | Within ±20% |
| 110/146 (75%) | 141/146 (97%) | 146/146 (100%) | 146/146 (100%) |

Clinician DORSAL HAND vs YSI 2300

| | | | |
|---|-------------------|------------------|-------------------|
| 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% |
| 118/146 (81%) | 145/146 (99%) | 145/146 (99%) | 146/146 (100%) |

Table 2. Data analysis at VENTRAL PALM

Patient VENTRAL PALM vs YSI 2300

| | | | |
|---|-------------------|------------------|-------------|
| 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% |

| | | | | |
|------------------|------------------|-------------------|-------------------|--|
| 101/146 (69%) | 138/146 (95%) | 146/146 (100%) | 146/146 (100%) | |
|------------------|------------------|-------------------|-------------------|--|

Clinician VENTRAL PALM vs YSI 2300

| | | | | |
|---|------------------|-------------------|-------------------|------------------|
| 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% | |
| 114/146 (78%) | 143/146 (98%) | 146/146 (100%) | 146/146 (100%) | |

Table 3. Data analysis at UPPER ARM

Patient UPPER ARM vs YSI 2300

| | | | | |
|---|------------------|-------------------|-------------------|------------------|
| System accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L) | | | | |
| 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%) | 137/146 (94%) | 145/146 (99%) | 146/146 (100%) | |

Clinician UPPER ARM vs YSI 2300

| | | | | |
|---|------------------|-------------------|-------------------|------------------|
| 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% | |
| 85/146 (58%) | 136/146 (93%) | 145/146 (99%) | 146/146 (100%) | |

Table 4. Data analysis at FOREARM

Patient FOREARM vs YSI 2300

| 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%) | 137/146 (94%) | 144/146 (99%) | 146/146 (100%) |

Clinician FOREARM vs YSI 2300

| 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%) | 138/146 (95%) | 146/146 (99%) | 146/146 (100%) |

Table 5. Data analysis at THIGH

Patient THIGH vs YSI 2300

| 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% |
| 116/146 (79%) | 144/146 (99%) | 146/146 (100%) | 146/146 (100%) |

Clinician THIGH vs YSI 2300

| 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 $\pm 5\%$ | Within $\pm 10\%$ | Within $\pm 15\%$ | Within $\pm 20\%$ |
| 116/146 (79%) | 146/146 (100%) | 146/146 (100%) | 146/146 (100%) |

Table 6. Data analysis at CALF

Patient CALF vs YSI 2300

| System accuracy results for glucose concentration < 75 mg/dL | | | |
|---|-----------------------|-----------------------|-------------------|
| Within ± 5 mg/dL | Within ± 10 mg/dL | Within ± 15 mg/dL | |
| 3/4(75%) | 4/4(100%) | 4/4(100%) | |
| System accuracy results for glucose concentration ≥ 75 mg/dL | | | |
| Within $\pm 5\%$ | Within $\pm 10\%$ | Within $\pm 15\%$ | Within $\pm 20\%$ |
| 111/146 (76%) | 143/146 (98%) | 146/146 (100%) | 146/146 (100%) |

Clinician CALF vs YSI 2300

| System accuracy results for glucose concentration < 75 mg/dL | | | |
|---|-----------------------|-----------------------|-------------------|
| Within ± 5 mg/dL | Within ± 10 mg/dL | Within ± 15 mg/dL | |
| 3/4(75%) | 4/4(100%) | 4/4(100%) | |
| System accuracy results for glucose concentration ≥ 75 mg/dL | | | |
| Within $\pm 5\%$ | Within $\pm 10\%$ | Within $\pm 15\%$ | Within $\pm 20\%$ |
| 127/146 (87%) | 145/146 (99%) | 146/146 (100%) | 146/146 (100%) |

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Expected blood glucose values for normal people without diabetes are as below:

Fasting and before meal: Less than 100 mg/dL (5.6 mmol/L)

2 hours after meal: Less than 140 mg/dL (7.8 mmol/L)

American Diabetes Association (2010), Clinical Practice Recommendations, Diabetes Care 34 (Supplement 1): S11-S61.

N. Instrument Name:

Healthpro™ 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 _____

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 fingertip, which is directly applied to the test strip.

5. Calibration:

The device must be coded with the code found on the current test strip label. No further calibration is required.

6. Quality Control:

There are three levels of glucose control solution (Level 1, 2 and 3) of which Level 2 is included with the test kit and can be run with this device. 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. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. Hematocrit Study: The effect of different hematocrit levels on the performance of the Healthpro™ Blood Glucose Monitoring System was evaluated using venous whole blood samples with hematocrit levels of 20, 30, 40, 50 and 60% spiked with glucose to achieve 8 concentrations ranging from 32 to 530 mg/dL (32, 73, 121, 185, 253, 371, 459 and 530 mg/dL). Each sample was then tested 15 times and the values were compared with those obtained from YSI 2300. The % biases relative to YSI were acceptable within the claimed hematocrit range of 20 to 60%.

2. Altitude study: Venous whole blood samples collected from donors were spiked with glucose to whole blood target levels of approximately 66, 220 and 349 mg/dL. Blood glucose target concentrations were then verified by the reference YSI glucose analyzer. Glucose measurements were obtained using the Healthpro™ Blood Glucose Monitoring System in an altitude chamber with adjusted pO₂ from 156 to 71 mmHg by tonometry method blowing humidified mixed gas (O₂, CO₂ and N₂) into the blood sample to adjust the pO₂ level of the blood. The results demonstrate acceptable bias to YSI to support the claims in the labeling that altitudes up to 10,000 feet have no significant effect on blood glucose measurements from the Healthpro™ Blood Glucose Monitoring System.
3. Sample volume study: The sponsor performed a study to verify the test strip sample volume requirement and the test strip fill error requirement established for the Healthpro™ Blood Glucose Monitoring System. Blood samples were tested at six sample volumes (0.3, 0.5, 0.8, 1.0 and 1.5 µL) and values obtained were compared to YSI values. Results support the claimed sample volume of 0.5 µL and the error code for insufficient sample volume.
4. Temperature and humidity studies: The sponsor performed temperature and humidity studies using venous blood samples to evaluate temperatures ranging from 10°C to 40°C and relative humidity from 10% to 90%. Meter results were compared to YSI 2300 reference analyzer. Four temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, high temperature/low humidity and high temperature/high humidity. No significant effect (relative to YSI 2300 reference analyzer) was observed with the temperature and humidity combinations tested. The results support the claims in the labeling that the system can be used in conditions of 10 to 40°C with relative humidity of 10 to 90%.
5. Infection Control Studies: The device is intended for single-patient use. Disinfection efficacy studies were performed using materials that comprise the meter and lancing device by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B (HBV) with CaviWipes Disinfecting Towelettes with EPA registration #46781-8. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter and lancing device after 1,095 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate 3 years of meter and lancing device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.
6. The data transmission capability, data transmission port and Healthpro™ Software (firmware and communication) was evaluated in usability study and found to be acceptable. Additionally verification and validation of these functions were conducted and found to be acceptable.
7. EMC testing was evaluated and certified by UL Verification Service and Verification of Compliance certificates provided.
8. Flesch-Kincaid readability assessment was conducted and the results demonstrated that the User Manual, test strip package insert and control solution package insert were written at the 7.8, 7.9 and 7.6 grade levels respectively.

9. Customer service is available 24 hours a day, 7 days a week by calling 1-888-446-3246.

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.