

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

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

k082020

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Whole blood glucose

**D. Type of Test:**

Quantitative glucose oxidase

**E. Applicant:**

Infopia Co., Ltd.

**F. Proprietary and Established Names:**

ENVISION™ 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:

75 (Clinical Chemistry)

**H. Intended Use:**

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The ENVISION™ Blood Glucose Testing System is for the quantitative measurement of the concentration of glucose in capillary whole blood taken from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh by diabetic patients or health care professionals as an aid in the management of diabetes. ENVISION™ Blood Glucose Testing System is for in vitro diagnostic use and is not to be used for the diagnosis of diabetes or for neonatal use. Alternate site testing should be done during steady-state times when glucose is not changing rapidly.

3. Special conditions for use statement(s):

For over-the-counter use.

Do not use neonate samples.

Inaccurate results may occur when in shock, hypotensive individuals, hyperglycemic, or hyperosmolar state, with or without ketosis.

Envision Blood Glucose Testing System is not to be used for the diagnosis or screening of diabetes.

Alternate site testing should be done during steady-state times when glucose is not changing rapidly: before meals and before bedtime. However, when blood glucose is changing, blood from the finger tip may show these changes sooner than blood from other sites.

4. Special instrument requirements:

Infopia Envision Blood Glucose Testing System

**I. Device Description:**

The ENVISION Blood Glucose Testing System consists of five main components: the blood glucose meter, test strips, control solutions (three levels of ENVISION control solutions), lancing device and lancets and the users manual with log book. The performance of the test

strips is verified by the control solutions. The controls were previously cleared in submission k051285.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
One Touch Ultra Blood Glucose Monitoring System
2. Predicate 510(k) number(s):  
k021819
3. Comparison with predicate:

| <b>Similarities</b> |   |                        |
|---------------------|---|------------------------|
| Item                | Device  | Predicate              |
| Detection method    | Amperometry: current is generated by oxidation of reduced mediator. | Amperometry            |
| Enzyme              | Glucose Oxidase   | Glucose Oxidase        |
| Mediator            | Potassium ferricyanide  | Potassium ferricyanide |
| Open Stability      | 3 months  | 3 months               |
| Weight              | 42g(including battery)  | 42g (with battery)     |
| Test range          | 20 - 600 mg/dL  | 20- 600 mg/dL          |
| Electrode           | Carbon electrode  | Carbon electrode       |

| <b>Differences</b>           |   |   |
|------------------------------|---|---|
| Item                         | Device  | Predicate   |
| Hematocrit Range             | 20 - 60%  | 30 - 55%  |
| Test Time                    | 9 seconds   | 5 seconds   |
| Sample Volume                | 1.5uL   | 1uL   |
| Temperature & Humidity range | 50 -104° F<br>10 - 40° C<br>10 - 90%              | 43 - 111° F<br>6 - 44° C<br>10 - 90%                |
| Coding                       | No Coding   | Coding  |
| Memory capability            | 7, 14, 21-day average and 365 tests in the memory | 14, 30-day average and last 150 tests in the memory |
| Power                        | 3V Li battery (CR2032x2)                          | 3V Li battery (CR2032)                              |
| Battery life                 | 1 year  | Running 1,000 test                                  |
| Size: LxWxH (mm)             | 77x42x19  | 80x57x21  |
| Software                     | ENVISION™<br>Diabetes management software         | ONETOUCH® diabetes management software              |

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

ISO 15157:2003 In vitro diagnostic test systems- Requirement 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 60068-2-64:1993 Environmental Testing- Part 2.

IEC 61010-1:2001 Safety Requirements for electrical equipment for measurement, control and laboratory use.

IEC 61326:2002 Electrical equipment for electrical equipment for measurement, control and laboratory use.

**L. Test Principle:**

The ENVISION Blood Glucose Test System is based on the measurement of glucose concentration in human blood. The principle of the test is based on the reaction between glucose in blood sample, glucose oxidase and potassium ferricyanide. The resulting product generates a 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):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Within- in precision was measured with EDTA anti-coagulated venous blood samples at five different glucose concentrations. Five hundred test strips from 10 vials from a single lot were tested with 10 meters. Ten measurements for five samples (n=50) were recorded and the results are shown in the table below.

| With-in precision |          |          |          |          |          |
|-------------------|----------|----------|----------|----------|----------|
|                   | Sample 1 | Sample 2 | Sample 3 | Sample 4 | Sample 5 |
| Mean              | 41.5     | 79.4     | 127.6    | 204.7    | 319.3    |
| SD                | 1.1      | 1.5      | 2.2      | 4.0      | 8.1      |
| CV                | 2.7      | 1.9      | 1.7      | 2.0      | 2.5      |

Between-day precision was measured by measuring three levels of control materials daily for ten days (n=90) on three separate meters. The results are summarized in the table below.

| Between-day precision |          |          |          |
|-----------------------|----------|----------|----------|
|                       | Sample 1 | Sample 2 | Sample 3 |
| Mean                  | 49       | 108      | 296      |
| SD                    | 1.1      | 1.3      | 6.4      |
| CV                    | 2.2      | 1.2      | 2.1      |

*b. Linearity/assay reportable range:*

EDTA venous blood sample was spiked to form two concentrations (high and low). The two concentrations were mixed to form 14 glucose concentrations between 20.4 to 595.8 mg/dL (confirmed by YSI) then tested with the ENVISION Blood Glucose Meter and YSI. The meter displays “Low” with glucose values below 20 mg/dL, “Hi” with glucose values over 600 mg/dL. Each glucose level was measured 5 times by the ENVISION Meter and in duplicate by YSI. Regression analysis showed a linear relationship between the ENVISION Meter and the YSI method:  $y=0.998x - 0.880$ ,  $R^2=1$ .

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

The glucose control standards are traceable to a NIST glucose standard and were previously cleared in submission k051285. 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. 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.

Shelf-life studies show that the unopened test strips have a 26 month life-span and 3 months shelf-life once a vial of strips is opened. Unopened controls have a 26 month shelf life and are stable for 3 months after first use.

*d. Detection limit:*

The sponsor has not conducted studies to determine the limit of detection (LOD). However, the lower limit is supported by linearity studies. The sponsor has established the measuring range of 20 – 600 mg/dL for ENVISION Blood Glucose Test System.

*e. Analytical specificity:*

The sponsor evaluated the effects of hematocrit on whole blood samples spiked with 4 to 5 hematocrit levels (between 20 -60%) at eight glucose concentrations between 45 to 559 mg. These values were compared to values from an YSI-2300 analyzer. The results indicated that bias introduced at hematocrit levels between 20% to 60% was within +/-15 mg/dL for values under 75 mg/dL and +/-10% for values 75 mg/dL and over.

A temperature study was conducted with three control solutions kept at room temperature. Five meters and strips were set to three different temperatures between 10 and 40°C. A humidity study was conducted with three glucose levels run at three humidity percentages. The results from both studies showed that the device can be used from 10 to 40°C and from 10 to 90% relative humidity.

The sponsor conducted an altitude study to evaluate the effects of decreased oxygen pressure resulting from high altitudes may have on the device. An altitude study was performed with venous blood samples from volunteers. Glucose values of adjusting pO<sub>2</sub> venous bloods (ranging from 32 mg/dL to 551 mg/dL) were measured by ENVISION™ in the altitude chamber at sea level and 10,000 feet conditions. Glucose values of plasma centrifuged from venous whole blood were measured by YSI 2300 as the reference value. Linear regression results of the Envision versus the YSI results at 10000 feet revealed a line of  $y = 0.9949x - 1.09$  and a correlation coefficient of 0.9990. The test data using the samples from both meters (sea-level and 10000 feet) showed that the bias versus YSI at 10,000 feet is the same bias versus YSI as that observed at sea level. These data indicate no additional effect due to altitude up to 10,000 feet. The results indicate that the device is unaffected by altitudes up to 10,000 feet.

Common interferences were evaluated by spiking venous blood with glucose to three concentrations based on EP7-P of low (less than 75 mg/dL) normal (160 mg/dL) and high (greater than 240 mg/dL). Middle concentrations were prepared gravimetrically from the two initial concentrations to form 5 total concentrations. The glucose samples were spiked with the interferences and run in replicates of 5. The sponsor's acceptance criterion was +/-15% bias. There was no interference effects observed up to the high test levels show in the table below. The error% of uric acid, Dopamine and Gentistic acid was over  $\pm 15\%$ , failing the criteria. Thus, uric acid, Dopamine and Gentistic acid were included as an interference in the strip user manual. The three interferences studies are shown in the three tables below.

| Interferences  | Interference substance               | Mean of Test Results |              |                     |
|----------------|--------------------------------------|----------------------|--------------|---------------------|
|                | High Interference Test Level (mg/dL) | Low (mg/dL)          | High (mg/dL) | Difference* (mg/dL) |
| Acetaminophen  | <u>20</u>                            | 44.8                 | 48.2         | <u>3.4</u>          |
| Bilirubin      | <u>40</u>                            | 45.8                 | 48.8         | <u>3.0</u>          |
| Gentistic acid | <u>50</u>                            | 44.8                 | 53.8         | <u>9.0</u>          |
| Levo-Dopa      | <u>4</u>                             | 46.2                 | 47.2         | <u>1.0</u>          |
| Methyl-Dopa    | <u>2.5</u>                           | 46.2                 | 47.8         | <u>1.6</u>          |
| Tolazamide     | <u>5</u>                             | 45.8                 | 46.8         | <u>1.0</u>          |
| Dopamine       | <u>13</u>                            | 44.8                 | 53.4         | <u>8.6</u>          |
| Ascorbate      | <u>3</u>                             | 44.8                 | 48.2         | <u>3.4</u>          |
| EDTA           | <u>640</u>                           | 44.8                 | 47.0         | <u>2.2</u>          |
| Glutathione    | <u>1</u>                             | 44.8                 | 49.4         | <u>4.6</u>          |

|                |              |      |      |            |
|----------------|--------------|------|------|------------|
| Heparin        | <u>1,000</u> | 44.8 | 47.0 | <u>2.2</u> |
| Ibuprofen      | <u>40</u>    | 44.6 | 48.8 | <u>4.2</u> |
| Salicylic acid | <u>50</u>    | 44.8 | 47.4 | <u>2.6</u> |
| Tetracycline   | <u>0.4</u>   | 44.8 | 47.8 | <u>3.0</u> |
| Tolbutamide    | <u>100</u>   | 44.6 | 49.2 | <u>4.6</u> |
| Urea           | <u>500</u>   | 44.8 | 49.4 | <u>4.6</u> |
| Uric acid      | <u>20</u>    | 45.8 | 52.2 | <u>6.4</u> |
| Creatinine     | <u>30</u>    | 44.8 | 47.4 | <u>2.6</u> |
| Cholesterol    | <u>500</u>   | 46.0 | 50.2 | <u>4.2</u> |
| TG             | <u>3000</u>  | 45.8 | 49.6 | <u>3.8</u> |
| Glactose       | <u>50</u>    | 44.8 | 48.6 | <u>3.8</u> |
| Xylose         | <u>10</u>    | 44.8 | 49.0 | <u>4.2</u> |
| Maltose        | <u>300</u>   | 44.8 | 48.0 | <u>3.2</u> |

\* Difference(mg/dL) = (assay value with interference substance – assay value without interference substance)

Normal:

| Interferences  | Interference substance               | Mean of Test Results |              |                 |
|----------------|--------------------------------------|----------------------|--------------|-----------------|
|                | High Interference Test Level (mg/dL) | Low (mg/dL)          | High (mg/dL) | Difference* (%) |
| Acetaminophen  | <u>20</u>                            | 160.6                | 160.6        | <u>7.3</u>      |
| Bilirubin      | <u>40</u>                            | 163.4                | 163.4        | <u>7.1</u>      |
| Gentistic acid | <u>50</u>                            | 160.6                | 160.6        | <u>17.7</u>     |
| Levo-Dopa      | <u>4</u>                             | 160.8                | 160.8        | <u>2.0</u>      |
| Methyl-Dopa    | <u>2.5</u>                           | 160.8                | 160.8        | <u>3.1</u>      |
| Tolazamide     | <u>5</u>                             | 163.4                | 163.4        | <u>1.8</u>      |
| Dopamine       | <u>13</u>                            | 160.6                | 160.6        | <u>17.7</u>     |
| Ascorbate      | <u>3</u>                             | 160.6                | 160.6        | <u>4.1</u>      |
| EDTA           | <u>640</u>                           | 160.6                | 160.6        | <u>2.9</u>      |
| Glutathione    | <u>1</u>                             | 160.6                | 160.6        | <u>6.4</u>      |
| Heparin        | <u>1,000</u>                         | 160.6                | 160.6        | <u>2.5</u>      |
| Ibuprofen      | <u>40</u>                            | 161.4                | 161.4        | <u>10.0</u>     |
| Salicylic acid | <u>50</u>                            | 160.6                | 160.6        | <u>3.6</u>      |
| Tetracycline   | <u>0.4</u>                           | 160.6                | 160.6        | <u>6.5</u>      |
| Tolbutamide    | <u>100</u>                           | 161.4                | 161.4        | <u>11.4</u>     |
| Urea           | <u>500</u>                           | 160.6                | 160.6        | <u>9.1</u>      |

|             |             |       |       |             |
|-------------|-------------|-------|-------|-------------|
| Uric acid   | <u>20</u>   | 163.4 | 163.4 | <u>15.1</u> |
| Creatinine  | <u>30</u>   | 160.6 | 160.6 | <u>6.1</u>  |
| Cholesterol | <u>500</u>  | 160.0 | 160.0 | <u>6.3</u>  |
| TG          | <u>3000</u> | 162.0 | 162.0 | <u>5.1</u>  |
| Galactose   | <u>50</u>   | 160.6 | 160.6 | <u>5.2</u>  |
| Xylose      | <u>10</u>   | 160.6 | 160.6 | <u>5.1</u>  |
| Maltose     | <u>300</u>  | 160.6 | 160.6 | <u>3.6</u>  |

\* Difference (%) = (assay value with interference substance – assay value without interference substance) x 100 / assay value without interference substance

High:

| Interference substance | Mean of Test Results                 |             |              |                 |
|------------------------|--------------------------------------|-------------|--------------|-----------------|
|                        | High Interference Test Level (mg/dL) | Low (mg/dL) | High (mg/dL) | Difference* (%) |
| Acetaminophen          | <u>20</u>                            | 307.8       | 328.8        | <u>6.8</u>      |
| Bilirubin              | <u>40</u>                            | 304.8       | 323.2        | <u>6</u>        |
| Gentistic acid         | <u>50</u>                            | 307.8       | 358.4        | <u>16.4</u>     |
| Levo-Dopa              | <u>4</u>                             | 306.4       | 315.0        | <u>2.8</u>      |
| Methyl-Dopa            | <u>2.5</u>                           | 306.4       | 316.8        | <u>3.4</u>      |
| Tolazamide             | <u>5</u>                             | 304.8       | 313.6        | <u>2.9</u>      |
| Dopamine               | <u>13</u>                            | 307.8       | 359.2        | <u>16.7</u>     |
| Ascorbate              | <u>3</u>                             | 307.8       | 319.0        | <u>3.6</u>      |
| EDTA                   | <u>640</u>                           | 307.8       | 315.8        | <u>2.6</u>      |
| Glutathione            | <u>1</u>                             | 307.8       | 324.4        | <u>5.4</u>      |
| Heparin                | <u>1,000</u>                         | 307.8       | 316.2        | <u>2.7</u>      |
| Ibuprofen              | <u>40</u>                            | 306.0       | 337.6        | <u>10.3</u>     |
| Salicylic acid         | <u>50</u>                            | 307.8       | 320.6        | <u>4.2</u>      |
| Tetracycline           | <u>0.4</u>                           | 307.8       | 325.2        | <u>5.7</u>      |
| Tolbutamide            | <u>100</u>                           | 306.0       | 337.0        | <u>10.1</u>     |
| Urea                   | <u>500</u>                           | 307.8       | 333.8        | <u>8.4</u>      |
| Uric acid              | <u>20</u>                            | 304.8       | 343.0        | <u>12.5</u>     |
| Creatinine             | <u>30</u>                            | 307.8       | 324.4        | <u>5.4</u>      |
| Cholesterol            | <u>500</u>                           | 305.0       | 320.6        | <u>5.1</u>      |
| TG                     | <u>3000</u>                          | 303.0       | 320.0        | <u>5.6</u>      |
| Galactose              | <u>50</u>                            | 307.8       | 323.4        | <u>5.1</u>      |
| Xylose                 | <u>10</u>                            | 307.8       | 322.8        | <u>4.9</u>      |
| Maltose                | <u>300</u>                           | 307.8       | 318.4        | <u>3.4</u>      |

\* Difference (%) = (assay value with interference substance – assay value without interference substance) x 100 / assay value without interference substance

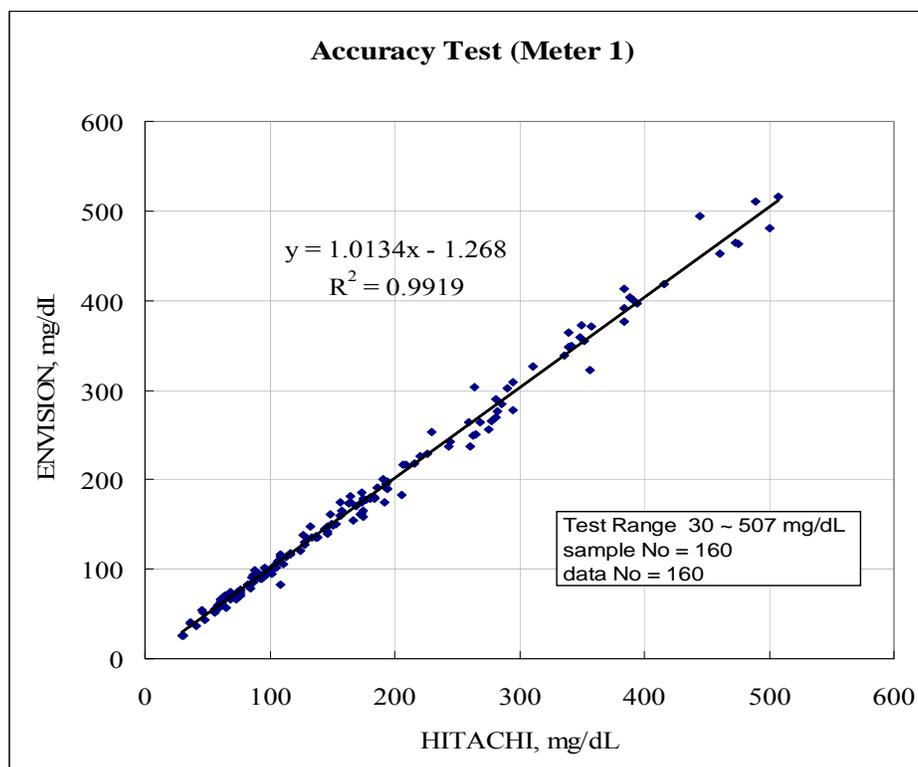
f. Assay cut-off:

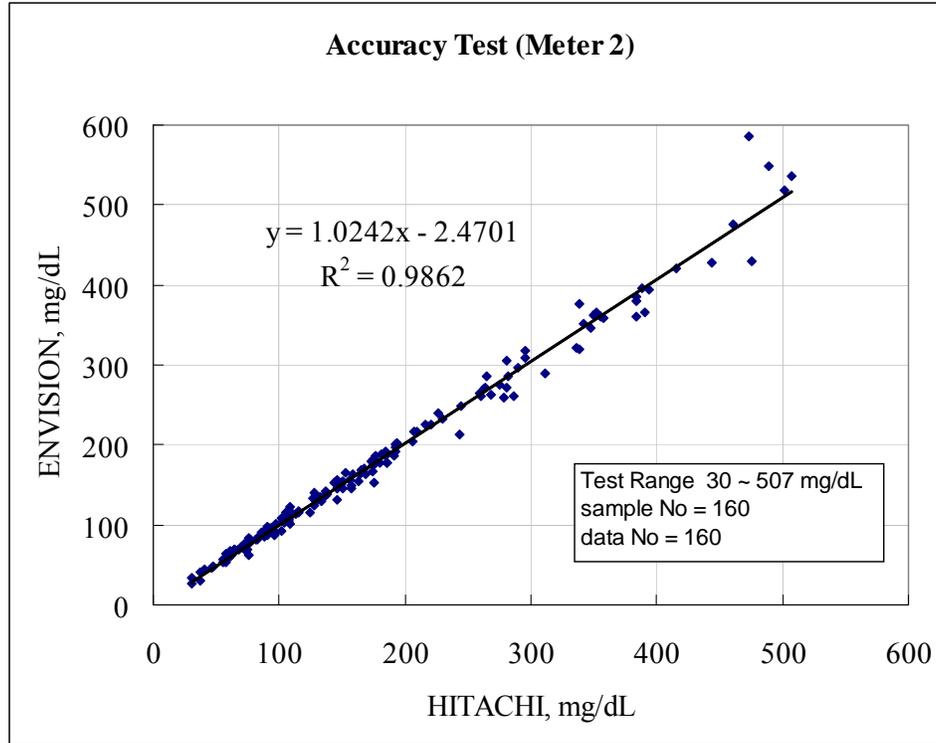
Not applicable.

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 by a Hitachi 747. Samples ranged from 30 to 507 mg/dL and were run on two different meters. . For some of the samples that were less than 50 mg/dL and greater than 400 mg/dL, pooled anti-coagulated capillary whole blood specimens were allowed to hydrolyze or were spiked to the desired glucose levels. Regression analysis of results from both meters is shown below:





95% of the individual glucose results were within the ISO 15197 criteria specifying that 95% of samples are within +/- 15 mg/dL when glucose concentration less than 75 mg/dL and within +/- 20% glucose concentration  $\geq 75$  mg/dL.

**System accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L)**

| Within $\pm 5$ mg/dL<br>(within $\pm 0.28$ mmol/L) | Within $\pm 10$ mg/dL<br>(within $\pm 0.56$ mmol/L) | Within $\pm 15$ mg/dL<br>(within $\pm 0.83$ mmol/L) |
|--|---|---|
| 38/56 (68 %)                                       | 56/56(100 %)  | 56/56(100 %)  |

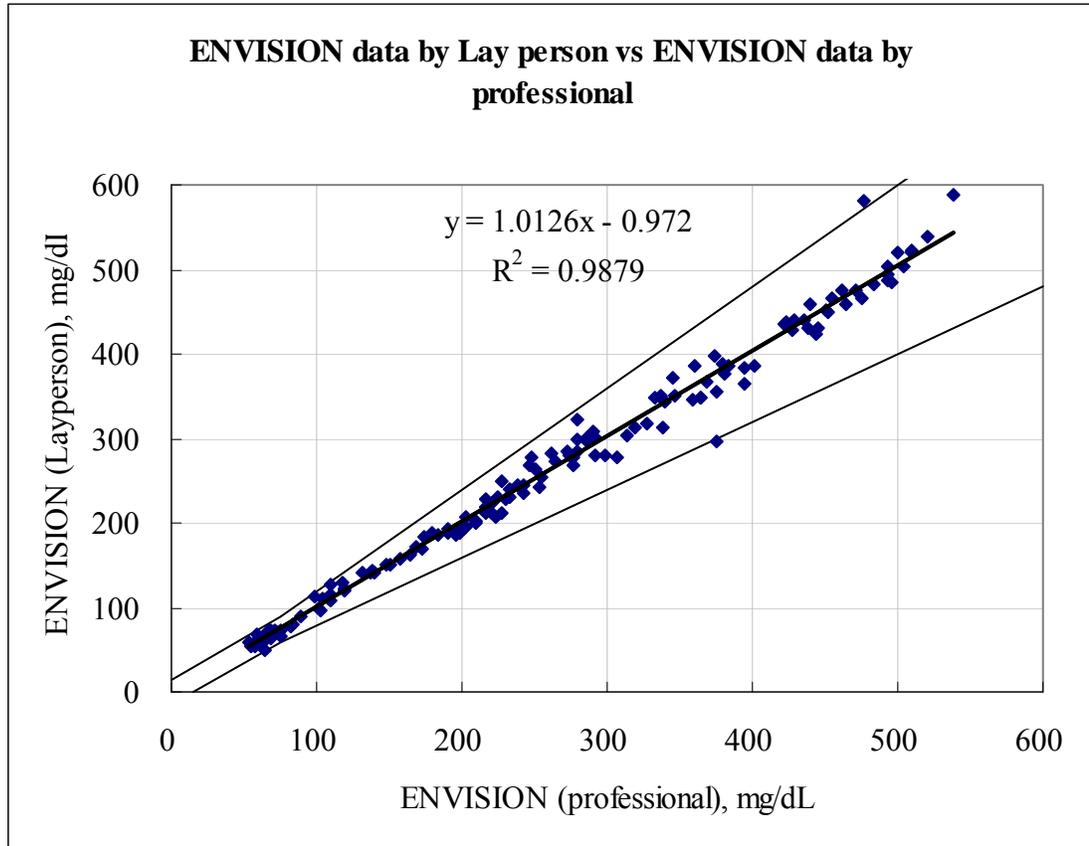
**System accuracy results for glucose concentration  $\geq 75$  mg/dL (4.2 mmol/L)**

| Within $\pm 5\%$ | Within $\pm 10\%$ | Within $\pm 15\%$ | Within $\pm 20\%$ |
|------------------|-------------------|-------------------|-------------------|
| 188/264(71%)     | 245/264(93%)      | 260/264(98%)      | 262/264(99%)      |

**Lay user studies:**

The sponsor conducted a study at three clinical sites (50 users per site) to compare the accuracy of glucose measurement between the lay-user and the healthcare professionals. At each clinical site, the lay-user performed a fingerstick, tested their blood with the ENVISION meter and recorded their results. A healthcare professional then obtained a capillary blood sample and a venous sample to obtain results with the same ENVISION meter and the Hitachi 747. 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 59-540 mg/dL) against a laboratory method (Hitachi 747) yielded the following results:  $y=1.00224x-$

2.392, R2=0.9843. The results (shown below the graphs) for the user versus healthcare results were within the ISO 15197 criteria of individual differences within +/- 15 mg/dL when glucose concentration less than 75 mg/dL and within +/- 20% glucose concentration  $\geq$ 75 mg/dL.



System accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L)

| Within $\pm$ 5mg/dL<br>(within $\pm$ 0.28 mmol/L) | Within $\pm$ 10 mg/dL<br>(within $\pm$ 0.56 mmol/L) | Within $\pm$ 15mg/dL<br>(within $\pm$ 0.83 mmol/L) |
|---|---|--|
| 18/25 (72 %)                                      | 24/25(96 %)   | 24/25(96%)   |

System accuracy results for glucose concentration  $\geq$ 75 mg/dL (4.2 mmol/L)

| Within $\pm$ 5% | Within $\pm$ 10% | Within $\pm$ 15% | Within $\pm$ 20% |
|-----------------|------------------|------------------|------------------|
| 93/125(74%)     | 117/125(94%)     | 121/125(97%)     | 123/125(98%)     |

The sponsor assessed readability of the labeling by the previously recruited 150 lay users who were provided with the ENVISION test kit. Participants varied in age, education, country of origin and gender. The overall survey indicated that 88% of the participants found the labeling easy to use and understand. The readability for the user manual, strip manual and control solution labeling are grades 6.5, 7.0 and 5.5, respectively.

Alternate Site Studies (AST):

The sponsor conducted alternative site testing (AST) using the ventral palm, the dorsal hand, the forearm, the upper arm, the calf, and the thigh and compared the results to concurrent fingerstick readings. Lay-users vigorously rubbed the alternative site for 5-10 seconds (until they felt warming) before obtaining the sample. Regression results are shown below and the percentage of results meeting ISO 15197 acceptance criteria for accuracy.

| Comparison              | N   | Range (mg/dL) | Regression       | R <sup>2</sup> |
|-------------------------|-----|---------------|------------------|----------------|
| Ventral palm vs. finger | 100 | 66-488        | Y=1.0056x-1.0066 | 0.9817         |
| Dorsal hand vs. finger  | 100 | 61-474        | Y=0.9795x+2.7119 | 0.9908         |
| Total hand vs. finger   | 200 | 61-488        | Y=0.9932x+0.859  | 0.9862         |
| Forearm vs. finger      | 100 | 62-470        | Y=0.9933x+1.3844 | 0.989          |
| Upper arm vs. finger    | 100 | 59-478        | Y=1.0081x-2.6555 | 0.9884         |
| Total arm               | 200 | 59-478        | Y=1.00x-0.3617   | 0.9889         |
| Calf vs. finger         | 100 | 52-456        | Y=1.0044x-0.3139 | 0.9853         |
| Thigh vs. finger        | 100 | 60-470        | Y=0.9881x+2.4037 | 0.977          |
| Total leg vs. finger    | 200 | 52-470        | Y=0.9945+1.3495  | 0.9815         |

Data analysis with finger capillary blood and palm blood

**ENVISION™ (DORSAL HAND) vs ENVISION™ (FINGER)**

System accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L)

| Within ± 5mg/dL<br>(within ± 0.28 mmol/L) | Within ± 10 mg/dL<br>(within ± 0.56 mmol/L) | Within ± 15mg/dL<br>(within ± 0.83 mmol/L) |
|---|---|--|
| 7/8 (88 %)                                | 8/8(100 %)                                  | 8/8(100%)                                  |

System accuracy results for glucose concentration ≥75 mg/dL (4.2 mmol/L)

| Within ±5% | Within ±10% | Within ±15% | Within ±20% |
|------------|-------------|-------------|-------------|
| 60/92(65%) | 82/92(89%)  | 90/92(98%)  | 91/92(99%)  |

**ENVISION™ (VENTRAL PALM) vs ENVISION™ (FINGER)**

System accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L)

| Within ± 5mg/dL<br>(within ± 0.28 mmol/L) | Within ± 10 mg/dL<br>(within ± 0.56 mmol/L) | Within ± 15mg/dL<br>(within ± 0.83 mmol/L) |
|---|---|--|
|   |   |  |

|             |             |             |
|-------------|-------------|-------------|
| 9/9 (100 %) | 9/9 (100 %) | 9/9 (100 %) |
|-------------|-------------|-------------|

System accuracy results for glucose concentration  $\geq 75$  mg/dL (4.2 mmol/L)

| Within $\pm 5\%$ | Within $\pm 10\%$ | Within $\pm 15\%$ | Within $\pm 20\%$ |
|------------------|-------------------|-------------------|-------------------|
| 64/91(70%)       | 82/91(90%)        | 90/91(99%)        | 90/91(99%)        |

### ENVISION™ (PALM) vs ENVISION™ (FINGER)

System accuracy results for glucose concentration  $< 75$  mg/dL (4.2 mmol/L)

| Within $\pm 5$ mg/dL<br>(within $\pm 0.28$ mmol/L) | Within $\pm 10$ mg/dL<br>(within $\pm 0.56$ mmol/L) | Within $\pm 15$ mg/dL<br>(within $\pm 0.83$ mmol/L) |
|--|---|---|
| 16/17 (94 %)                                       | 17/17(100 %)  | 17/17(100%)   |

System accuracy results for glucose concentration  $\geq 75$  mg/dL (4.2 mmol/L)

| Within $\pm 5\%$ | Within $\pm 10\%$ | Within $\pm 15\%$ | Within $\pm 20\%$ |
|------------------|-------------------|-------------------|-------------------|
| 124/183(68%)     | 164/183(90%)      | 180/183(98%)      | 181/183(99%)      |

Data analysis with finger capillary blood and arm blood

### ENVISION™ (FOREARM) vs ENVISION™ (FINGER)

System accuracy results for glucose concentration  $< 75$  mg/dL (4.2 mmol/L)

| Within $\pm 5$ mg/dL<br>(within $\pm 0.28$ mmol/L) | Within $\pm 10$ mg/dL<br>(within $\pm 0.56$ mmol/L) | Within $\pm 15$ mg/dL<br>(within $\pm 0.83$ mmol/L) |
|--|---|---|
| 4/9(44 %)  | 9/9(100 %)  | 9/9(100%)   |

System accuracy results for glucose concentration  $\geq 75$  mg/dL (4.2 mmol/L)

| Within $\pm 5\%$ | Within $\pm 10\%$ | Within $\pm 15\%$ | Within $\pm 20\%$ |
|------------------|-------------------|-------------------|-------------------|
| 63/91(69%)       | 88/91(97%)        | 89/91(98%)        | 90/91(99%)        |

### ENVISION™ (UPPERARM) vs ENVISION™ (FINGER)

System accuracy results for glucose concentration  $< 75$  mg/dL (4.2 mmol/L)

| Within $\pm 5$ mg/dL<br>(within $\pm 0.28$ mmol/L) | Within $\pm 10$ mg/dL<br>(within $\pm 0.56$ mmol/L) | Within $\pm 15$ mg/dL<br>(within $\pm 0.83$ mmol/L) |
|--|---|---|
| 7/8 (88 %)   | 7/8 (88 %)  | 8/8 (100 %)   |

System accuracy results for glucose concentration  $\geq 75$  mg/dL (4.2 mmol/L)

| Within $\pm 5\%$ | Within $\pm 10\%$ | Within $\pm 15\%$ | Within $\pm 20\%$ |
|------------------|-------------------|-------------------|-------------------|
| 69/92(75%)       | 89/92(97%)        | 91/92(99%)        | 91/92(99%)        |

### ENVISION™ (ARM) vs ENVISION™ (FINGER)

System accuracy results for glucose concentration  $< 75$  mg/dL (4.2 mmol/L)

| Within $\pm 5$ mg/dL<br>(within $\pm 0.28$ mmol/L) | Within $\pm 10$ mg/dL<br>(within $\pm 0.56$ mmol/L) | Within $\pm 15$ mg/dL<br>(within $\pm 0.83$ mmol/L) |
|--|---|---|
| 11/17 (65 %)                                       | 16/17 (94 %)  | 17/17 (100 %)                                       |

System accuracy results for glucose concentration  $\geq 75$  mg/dL (4.2 mmol/L)

|              |              |              |              |
|--------------|--------------|--------------|--------------|
| Within ±5%   | Within ±10%  | Within ±15%  | Within ±20%  |
| 132/183(72%) | 177/183(97%) | 180/183(98%) | 181/183(99%) |

Data analysis with finger capillary blood and leg blood

**ENVISION™ (CALF) vs ENVISION™ (FINGER)**

System accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L)

|   |   |  |
|---|---|--|
| Within ± 5mg/dL<br>(within ± 0.28 mmol/L) | Within ± 10 mg/dL<br>(within ± 0.56 mmol/L) | Within ± 15mg/dL<br>(within ± 0.83 mmol/L) |
| 6/6 (100 %)                               | 6/6 (100 %)                                 | 6/6 (100 %)                                |

System accuracy results for glucose concentration ≥75 mg/dL (4.2 mmol/L)

|            |             |             |             |
|------------|-------------|-------------|-------------|
| Within ±5% | Within ±10% | Within ±15% | Within ±20% |
| 63/94(67%) | 89/94(95%)  | 92/94(98%)  | 92/94(98%)  |

**ENVISION™ (THIGH) vs ENVISION™ (FINGER)**

System accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L)

|   |   |  |
|---|---|--|
| Within ± 5mg/dL<br>(within ± 0.28 mmol/L) | Within ± 10 mg/dL<br>(within ± 0.56 mmol/L) | Within ± 15mg/dL<br>(within ± 0.83 mmol/L) |
| 5/8 (63 %)                                | 7/8 (88 %)                                  | 8/8 (100 %)                                |

System accuracy results for glucose concentration ≥75 mg/dL (4.2 mmol/L)

|            |             |             |             |
|------------|-------------|-------------|-------------|
| Within ±5% | Within ±10% | Within ±15% | Within ±20% |
| 64/92(70%) | 87/92(95%)  | 89/92(97%)  | 90/92(98%)  |

**ENVISION™ (LEG) vs ENVISION™ (FINGER)**

System accuracy results for glucose concentration <75 mg/dL (4.2 mmol/L)

|   |   |  |
|---|---|--|
| Within ± 5mg/dL<br>(within ± 0.28 mmol/L) | Within ± 10 mg/dL<br>(within ± 0.56 mmol/L) | Within ± 15mg/dL<br>(within ± 0.83 mmol/L) |
| 11/14(79%)                                | 13/14(93 %)                                 | 14/14(100 %)                               |

System accuracy results for glucose concentration ≥75 mg/dL (4.2 mmol/L)

|              |              |              |              |
|--------------|--------------|--------------|--------------|
| Within ±5%   | Within ±10%  | Within ±15%  | Within ±20%  |
| 127/186(68%) | 176/186(95%) | 181/186(97%) | 182/186(98%) |

*b. Matrix comparison:*

Not applicable; this device is only indicated for capillary whole blood

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):*

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.<sup>1,2</sup>

1) Krall, L.P., and Beaser, R.S.: Joslin Diabetes Manual\ I. Philadelphia: Lea and Febiger(1989), 138

2) Beaser, R.S. and Hill, Joan:The Joslin Guide to Diabetes.New York: Simon and Schuster (1995), P158

**N. Instrument Name:**

ENVISION™ Blood Glucose Test System

**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  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 finger, ventral palm, the dorsal hand, the forearm, the upper arm, the calf, and the thigh. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

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

6. Quality Control:

The sponsor has three levels of controls available for this meter with both 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 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.

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

None

**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.