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

A. 510(k) Number:

k161790

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose from the fingertip

D. Type of Test:

Quantitative amperometric assay (Glucose oxidase)

E. Applicant:

Bionime Corporation

F. Proprietary and Established Names:

iGlucose Blood Glucose Monitoring 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

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indication(s) for use below

2. Indication(s) for use:

   The iGlucose Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The iGlucose Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

   The iGlucose 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 iGlucose Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes or for neonatal use.

   The iGlucose Blood Glucose Test Strips are for use with the iGlucose Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

3. Special conditions for use statement(s):

- For over-the-counter use
- The iGlucose Blood Glucose Monitoring System is not for use on neonates and should not be used in the critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients.
- Only for use with fresh capillary whole blood obtained from the fingertip.
- Inaccurate test results may be obtained at altitudes greater than 10,000 ft above sea level.
- Do not use at temperatures below 10°C (50°F) or above 40°C (104°F), nor below 10% or above 90% relative humidity.
- Hematocrits below 20% may cause higher results. Hematocrits above 60% may cause lower results.

- The iGlucose Blood Glucose Monitoring System should not be used to screen for or diagnose diabetes mellitus.

- For single-patient use only.

4. Special instrument requirements:

   Bionime iGlucose Blood Glucose Monitoring System

I. Device Description:

The iGlucose Blood Glucose Monitoring System is for single patient use only. The iGlucose Blood Glucose Monitoring System consists of the iGlucose meter, the iGlucose test strips and the Rightest Glucose Control Solutions (GC550 level 2 and 4 (previously cleared under k092052), lancets, meter charger with cable and a clear cap for the lancing device.

Each iGlucose test strip contains the following reagent composition: Glucose oxidase (Aspergillus niger) 14.8%, potassium ferricyanide 39.5%, and other non-reactive ingredients.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   GE Blood Glucose Monitoring System 333

2. Predicate 510(k) number(s):
   k143387

3. Comparison with predicate:

Similarities		
Item	iGlucose Blood Glucose Monitoring System Candidate Device	GE Blood Glucose Monitoring System 333 Predicate (k143387)
Indications for Use	For the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the fingertip as an aid to monitor the effectiveness of diabetes control.	Same
Detection Method	Amperometric	Same
Enzyme	Glucose oxidase	Same
Sample Type	Capillary blood	Same
Sample Volume	0.75 µL	Same
Measurement Range	20 – 600 mg/dL	Same

Similarities		
Item	iGlucose Blood Glucose Monitoring System Candidate Device	GE Blood Glucose Monitoring System 333 Predicate (k143387)
Hematocrit Range	20 – 60%	Same
Interferences	Ascorbic acid ≧ 5 mg/dL Cholesterol ≧ 600 mg/dL Uric acid ≥ 10 mg/dL	Same
Unit of Measurement	mg/dL	Same
Open Vial Shelf Life	3 months	Same
Test Time	5 seconds	Same
Coding	Auto coding	Same
Operating Temperature Range	50 ~104 °F (10 ~ 40℃)	Same
Operating Relative Humidity Range	10 ~ 90%	Same
Operating Altitude	Up to 10,000 ft	Same
Test Strip Storage Conditions	39 ~86 °F (4 ~ 30℃), 10 ~ 90% relative humidity	Same
Meter Storage Conditions	14 ~140 °F (-10 ~ 60℃)	Same
Memory Capacity	500 blood glucose test results with date and time	Same

Differences		
Item	iGlucose Blood Glucose Monitoring System Candidate Device	GE Blood Glucose Monitoring System 333 Predicate (k143387)
Power Supply	Rechargeable battery (3.7V, 1,000mAh Li-Ion)	Two 1.5V (AAA) batteries
Meter Dimensions	104 mm × 49.8 mm × 16.5 mm	85 mm × 57 mm × 22.5 mm
Meter Weight	85.0 ± 5 g with battery	81.0 ± 5 g with batteries
Battery Life	About 500 tests per battery charge without use of data transmission. Number of uses is reduced and varies when data is transmitted.	About 800 tests per battery life
LCD Display Area	36.6 mm × 49 mm	39 mm × 39.5 mm
Data Transmission	Global System for Mobile Communication	Bluetooth 4.0 (Low energy)
Power Saving	Automatically turns to standby mode	Turns to standby by pressing the main button for 3

Differences		
Item	iGlucose Blood Glucose Monitoring System Candidate Device	GE Blood Glucose Monitoring System 333 Predicate (k143387)
		seconds.
Backlight	Yes	No

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

CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition (2005)

CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (2014)

EN 61010-1, Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements (2001)

L. Test Principle:

The iGlucose Blood Glucose Monitoring System measures glucose amperometrically. The reaction of glucose oxidase and potassium ferricyanide in the test strip with glucose in the sample produces an electrical current which is proportional to the amount of glucose in the sample. The meter measures the current and converts it to the corresponding glucose concentration, which is displayed on the meter.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within-run (Repeatability)

Within-run precision studies were performed using venous whole blood samples of 5 glucose levels (30-50, 51-110, 111-150, 151-250, 251-400 mg/dL). Samples were tested ten times with each of three lots of single test strips with 10 meters for a total of 300 tests per glucose concentration and a grand total of 1500 tests.

Glucose Level (mg/dL)	Lot	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	1	44.4	1.6	3.6
	2	44.9	1.7	3.7
	3	43.8	1.6	3.5
51-110	1	99.7	1.8	1.8
	2	98.2	2.0	2.0
	3	94.9	2.2	2.3
111-150	1	133.2	2.1	1.5
	2	132.7	2.3	1.7
	3	131.7	2.7	2.0
151-250	1	212.6	3.1	1.5
	2	215.3	3.2	1.5
	3	211.5	4.1	2.0
251-400	1	363.2	5.0	1.4
	2	366.0	5.5	1.5
	3	362.8	5.9	1.6

Intermediate Precision

Intermediate (between run) precision was evaluated using three levels of glucose control solutions, 3 test strip lots, and 10 meters. Each control solution level was measured once a day for 10 days with each meter and test strip lot, for a total of 100 replicates per control solution level per test strip lot for a total of 300 replicate for each glucose control level. Results are summarized below:

Control Solution Level (mg/dL)	Lot	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	1	44.3	1.1	2.5
	2	41.6	1.2	3.0
	3	42.1	1.3	3.0
51-110	1	97.7	1.9	1.9
	2	96.1	2.0	2.1
	3	96.1	2.0	2.0
251-400	1	271.3	4.4	1.6
	2	276.8	4.6	1.6
	3	274.9	4.9	1.8

b. Linearity/assay reportable range:

Linearity was assessed with three lots of iGlucose Blood Glucose Test Strips. Each test strip lot was tested with three iGlucose Blood Glucose Monitoring Systems using blood samples spiked to 14 target analyte levels (19.7, 24.2, 43.4, 87.8, 144.0, 204, 256, 313, 358.5, 439, 486, 536, 561, 623.5 mg/dL). Each sample was measured in triplicate with each iGlucose Blood Glucose Monitoring System and measured in duplicate with a laboratory-based comparator method (YSI 2300 glucose analyzer).

The evaluation yielded the following regression equations for the three lots based on all samples:

$Y = 0.9952x – 0.4743$, $R^2 = 0.9996$

$Y = 0.9808x – 2.2286$, $R^2 = 0.9996$

$Y = 0.9889x – 3.0475$, $R^2 = 0.9997$

The results of the study support the sponsor's claimed glucose measuring range of 20-600 mg/dL. The meter displays "Lo" with glucose values below 20mg/dL, and "HI" with glucose values over 600 mg/dL. The "Lo" and "Hi" functions were validated and demonstrated to function as intended.

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

Traceability

The iGlucose Blood Glucose Monitoring System is s traceable to the NIST SRM 917c glucose reference material.

Test Strip Stability

Test Strip stability has been evaluated through accelerated and real-time open vial and closed vial studies. Protocols and acceptance criteria were reviewed and found to be acceptable. The manufacturer claims shelf life stability and open vial stability of 24 months from manufacture when stored at 40- 86°F (4-30˚C) and 10-90% relative humidity.

d. Detection limit:

See the linearity studies (section M.1.b.) above.

e. Analytical specificity:

Interference was evaluated at two glucose concentration intervals (60-100 and 150-300 mg/dL) by analyzing 19 potentially interfering exogenous and endogenous. Glucose values measured with the iGlucose Blood Glucose Monitoring System in samples spiked with a potentially interfering substance were compared with values measured in control samples (without potentially interfering substance) on the iGlucose Blood Glucose Monitoring System. The sponsor defined significant interference as of bias greater than ±10% (vs control condition). The compounds at the concentrations listed below did not demonstrate significant interference:

Based on these results, the sponsor includes the following in their test strip labeling:

Potential Interferent	Highest concentration tested at which no significant interference is observed (mg/dL)
Acetaminophen	20
Ascorbic Acid	5
Bilirubin	40
Cholesterol	600
Creatinine	10
Dopamine	2.5
Galactose	200
Ibuprofen	50
Icodextrin	500
L-dopa	3
Lactose	50
Maltose	1000
Methyldopa	1.6
Salicylate	20
Tetracycline	1.5
Tolbutamide	100
Triglyceride	1500
Uric acid	9
Xylose	100

High concentrations of Uric acid >9 mg/dL, Cholesterol >600 mg/dL, and Ascorbic acid (Vitamin C) >5 mg/dL may interfere with the glucose test causing inaccurate test results.

Certain conditions may cause your blood level of uric acid to rise. These conditions include gout or kidney disease. This means that when the uric acid concentration in your blood is greater than 9 mg/dL you may get inaccurate and unreliable glucose results. Please check with your doctor before using the iGlucose Blood Glucose Monitoring System.

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not Applicable

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):

User Performance Studies

To assess system accuracy of the iGlucose Blood Glucose Monitoring System, 153 lay users tested their own fingertip capillary blood samples. Results were compared to the measurements made using a laboratory-based comparator method (YSI 2300 analyzer). Samples ranged in glucose concentration from 46.0 - 546.3 mg/dL. The meter results relative to YSI are summarized below:

For glucose concentrations <75 mg/dL

Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL
1/6 (33%)	5/6 (83.3%)	6/6 (100.0%)

For glucose concentrations ≥75mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
64/149 (43.5%)	120/147 (81.6%)	140/147 (95.2%)	146/149 (98.0%)

$Y = 0.937x + 7.19$, $R^2 = 0.97$

4. Clinical cut-off**:**

   Not Applicable

5. Expected values/Reference range:

Expected glucose values for persons without diabetes:

Status	Range (mg/dL)
Fasting	<100 mg/dL
Two hours after meals	140 mg/dL

1) American Diabetes Association. Standards of Medical Care in Diabetes-2016. 2016;39 (supp. 1 Diabetes Care): S8-S16

N. Instrument Name:

iGlucose Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and requires a sample volume of 0.75 µL.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ____X____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No __X_____

2. Software:

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

   Yes __X_____ or No _____

3. Specimen Identification:
   There is no sample identification function with these devices. Samples are applied directly to the test strips as they are collected.

4. Specimen Sampling and Handling:

   The glucose test is intended to be used with capillary whole blood from the fingertip, palm or forearm. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:
   There is no calibration required by the user for the iGlucose Blood Glucose Monitoring System. The meter is automatically coded when the test strip is inserted into the meter.

6. Quality Control:

   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 labels. The user is cautioned not to use the meter if the control result falls outside these ranges. Control results are stored along with the blood results. The control solution tests are differentiated by a control solution symbol.

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

1. Sample Volume Study

To evaluate the minimal sample volume of the blood glucose test strips accuracy of the system with blood volumes of 0.60 µL, 0.65 µL, 0.70 µL, 0.75 µL, 0.80 µL, 1.00 µL, 1.25 µL, 2.00 µL, and 3.00 µL was assessed. Three blood glucose meters were used in this assessment and three lots of test strips to evaluate three blood glucose concentrations (50-75, 80 – 120 mg/dL, and 270 – 330 mg/dL). This testing supported the claimed sample volume of 0.75 for this device and that the sample detection feature functioned appropriately when the sample volume was <0.75uL.

2. Altitude Study

To evaluate the effects of altitude, three test strip lots were tested with 3 meters using three whole blood samples with glucose concentrations of 47.5-52.5, 92-100, and 283-307 mg/dL. The samples were tested at 0, 1000, 2000, and 3275 meters above sea level. Results obtained were compared with those obtained with a laboratory-based comparator method (YSI 2300 analyzer). The results demonstrate acceptable bias relative to the comparator method to support the claim in the labeling that altitudes up to 10,745 ft. (3275 meters) do not affect device performance..

3. Hematocrit Study

The effect of different hematocrit levels was evaluated using whole blood. iGlucose Blood Glucose Monitoring System was tested with venous blood at six glucose concentration intervals (20-50, 60-80, 135-165, 180-220, 270-330 and 360-440 mg/dL) and nine hematocrit levels (10, 20, 25, 30, 40, 55, 60, 65 and 70%). Each sample was measured in five replicates for each of three test strip lots also with an established a laboratory-based comparator method (YSI 2300). The average, standard deviation and coefficient of variance for above replicates in each test strip lot were calculated. Results of samples at each hematocrit level were

compared to samples measured with an established a laboratory-based comparator method (YSI 2300) and support the claimed hematocrit range of 20-60%.

4. Test System Operating Conditions

Three iGlucose Blood Glucose Monitoring System Meters were used to test venous blood sample with three lots of blood glucose test strips. Six test conditions were used in this study: 50 °C/ 10% RH, 50 °C/ 90% RH, 77 °C/ 10% RH, 77 °C/ 90% RH, 104 °C/ 10% RH, 104 °C/ 90% RH. The protocol and acceptance criteria for this test were found to be acceptable. The results supported the sponsor's claimed operating conditions of 50 °F-104 °F and a relative humidity range of 10% to 90%.

5. Readability Assessment

A readability assessment indicated a Flesch-Kincaid Score of 8 and lower for all instructional materials included with this device.

6. EMC Testing

The sponsor provided appropriate documentation certifying that electromagnetic (EMC) testing was performed and the device systems were found to be compliant.

7. Infection Control Studies

The device is intended for a single-patient use only. The disinfection efficacy was performed on the materials comprising the meter demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfecting agent, Cavi Wipes disinfecting towelettes (EPA Number 46781-8). Robustness studies were performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 550 cleaning and disinfection cycles (representing disinfection of the meter 8 times a month for 5 years, the expected lifetime of the meter) with Cavi Wipes disinfecting towelettes (EPA Number 46781-8). The subject device labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

8. This device was cleared after the FDA issued final guidance documents for prescription use blood glucose monitoring systems (BGMS) and over-the-counter use blood glucose monitoring systems (SMBG). However, the recommendations in the guidance documents were not followed for this device since the submission was received prior to the finalization of the guidance documents.

Q. Proposed Labeling:

The proposed labeling for this device is sufficient and satisfies the requirements for 21 CFR Part 809.10.

R. Conclusion:

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