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

A. 510(k) Number:

k143387

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose from the fingertip, forearm or palm

D. Type of Test:

Quantitative Amperometric assay (Glucose Oxidase)

E. Applicant:

Bionime Corporation

F. Proprietary and Established Names:

GE Blood Glucose Monitoring System 333

G. Regulatory Information:

1. Regulation section:

Product Code	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 Blood Glucose test system	Clinical Chemistry 75
CGA	Class II	21 CFR 862.1345 Glucose Oxidase, Glucose	Clinical Chemistry 75

H. Intended Use:

1. Intended use(s):

   See indication(s) for use below

2. Indication(s) for use:

The GE Blood Glucose Monitoring System 333 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. The GE Blood Glucose Monitoring System 333 is intended to be used by a single person and should not be shared.

The GE Blood Glucose Monitoring System 333 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 GE Blood Glucose Monitoring System 333 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The GE Blood Glucose Test Strips 333 is for use with the GE Blood Glucose Meter 333 to quantitatively measures glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm.

3. Special conditions for use statement(s):

   - Test Strips are designed for use with capillary whole blood samples. Do not use serum or plasma samples.
   - Not for screening or diagnosis of diabetes mellitus.
   - Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients.
   - Not for neonatal use
   - The glucose meter and lancing device are for single patient use. Do not use on multiple patients. Do not share meter or lancing device with anyone including other family members.
   - Alternate site testing should not be used to calibrate continuous glucose monitoring systems (CGMs).
   - Alternate site testing should only be done during steady-state times (when glucose is not changing rapidly).
   - Results from alternate site testing should not be used in insulin dose calculation.

4. Special instrument requirements:

   GE Blood Glucose Meter 333

I. Device Description:

The GE Blood Glucose Monitoring System 333 (for single patient use) consists of the following components: GE Blood Glucose Meter 333, GE Blood Glucose Test Strip 333 (sold separately), two levels of Rightest Control Solution GC550 (Level 2 and Level 4, previously cleared under k092052), lancets, lancing device, carrying case and User's manual.

Each GE Blood Glucose Test Strip 333 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):
   Rightest Blood Glucose Monitoring System GM550

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

   k092052

3. Comparison with predicate:

Similarities		
Item	Candidate Device GE Blood Glucose Monitoring System 333 (k143387)	Predicate Device Rightest Blood Glucose Monitoring System GM550 (k092052)
Intended Use / Indication for Use	It is intended to be used for quantitative measurement of glucose as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Measuring Range	20 – 600 mg/dL	Same
Sample Type / Site	Capillary whole blood (finger, forearm and palm)	Same
Measurement Technology	Oxidase Electrochemical Sensor	Same
Test Time	5 seconds	Same
Coding	Auto coding	Same
Operating Temperature Range	10 – 40 °C (50 - 104°F)	Same
Operating Relative Humidity Range	10 – 90%	Same
Altitude	0 to 10,745 feet (0 to 3275 meters)	Same
Memory Capacity	500 blood glucose test and control solution results with date and time	Same
Control solution	2 Levels (Levels 2 and 4)	Same

Differences		
Item	Candidate Device GE Blood Glucose Monitoring System (k143387)	Predicate Device Rightest Blood Glucose Monitoring System GM550 (k092052)
Hematocrit Range	20-60%	30-60%
Minimum Sample Volume	0.75 µL	1 µL
Wireless Module	Bluetooth 4.0 (Low energy)	No

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

- ISO 14971:2007, Medical devices – Application of risk management to medical devices.
- IEC 60601-1-2, Medical electrical equipment Part 1-2: General Requirements for Safety-Collateral Standard: Electromagnetic Compatibility- Requirements and tests.
- IEC 60601-1, Medical Electrical Equipment-Part 1: General Requirements for Safety.
- IEC 61000-4-2 Electromagnetic compatibility (EMC)-Part 4-2: Testing and measurement techniques-Electrostatic discharge immunity test.: 2008
- IEC 61000-4-3: Electromagnetic compatibility (EMC) – Part 4-3 2006+A1:2007: Testing and measurement techniques-Radiated, radio-frequency, electromagnetic field immunity test.
- IEC 61000-4-8, Electromagnetic compatibility (EMC)-Part 4-8: Testing and measurement techniques-Power frequency magnetic field immunity test.
- CLSI EP7-A2, Interference Testing in Clinical Chemistry; Approved Guideline.

L. Test Principle:

The GE Blood Glucose Monitoring System 333 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:

The sponsor performed within-run precision studies using venous blood samples diluted or spiked to five glucose concentrations (30-50, 51-110-, 111-150, 151-200, 251-400 mg/dL) across the claimed measuring range. Samples were tested using three lots of strips and 10 meters per test strip lot. Ten replicates were tested per meter, test strip lot and glucose concentration. Results are summarized below:

Within-run precision:

Glucose Level (mg/dL)	n	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
(30-50)	100	1	42.4	1.7	4.0
	100	2	45.6	1.7	3.8
	100	3	40.5	1.6	3.9
	Combined			1.7	3.9
(51-110)	100	1	90.2	1.5	1.6
	100	2	92.4	1.3	1.4
	100	3	89.0	1.3	1.5
	Combined			1.4	1.5
(111-150)	100	1	131.7	1.7	1.3
	100	2	130.9	1.7	1.3
	100	3	129.1	1.5	1.2
	Combined			1.7	1.3
(151-250)	100	1	215.1	3.1	1.4
	100	2	213.7	2.8	1.3
	100	3	212.6	3.2	1.5
	Combined			3.0	1.4
(251-400)	100	1	364.1	5.0	1.4
	100	2	357.7	4.6	1.3
	100	3	357.5	4.4	1.2
	Combined			4.7	1.3

Intermediate precision was evaluated using three lots of test strips and ten meters. Glucose controls solutions in three concentrations ranges (32-52, 82-115, 238-330 mg/dL) were used and each concentration was measured 10 times, with each of three test strip lots per day, for 10 days. The evaluation was completed by 2 operators (5 meters were used per operator). Results are summarized below:

Intermediate precision:

Control Level (mg/dL)	n	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
32-52	100	1	41.8	1.2	2.9
	100	2	42.0	1.3	3.1
	100	3	39.3	1.3	3.4
	Combined			1.3	3.1
82-115	100	1	96.9	1.6	1.6
	100	2	96.2	1.5	1.6
	100	3	94.0	1.5	1.6
	Combined			1.5	1.6
238-330	100	1	285.4	4.1	1.4
	100	2	282.1	4.2	1.5
	100	3	279.8	3.7	1.3
	Combined			4.0	1.4

b. *Linearity/assay reportable range:*

Linearity was evaluated using 3 test strip lots and 15 prepared venous blood glucose samples. Glucose concentrations of these levels measured using an established laboratory reference method (YSI 2300 Analyzer) was as follows: 0, 15, 23, 49, 91, 135, 193, 250, 302, 361, 405, 468, 538, 575, 604 mg/dL. Each glucose level was measured in triplicate with each of the 3 test strip lots and the values from the GE Blood Glucose Monitoring System 333 were compared with those obtained from the reference method. Results from regression analysis:

Test Strip Lot 1: $y = 0.9928x – 0.4439$; $R^2 = 0.9992$
Test Strip Lot 2: $y = 0.9886x + 0.0378$; $R^2 = 0.9987$
Test Strip Lot 3: $y = 0.9923x + 0.2624$; $R^2 = 0.9988$
$y= 0.9912x - 0.0479$; $R^2 = 0.9990$ for the three lots combined

The results of the study support the sponsors claimed glucose measuring range of 20-600 mg/dL. Data from the bench studies and software verification studies were provided to demonstrate that if a sample is less than 20 mg/dL glucose, the result displayed by the meter is "LO" and if the sample result exceeds 600 mg/dL glucose, the result displayed by the meter is "HI."

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

Traceability

The GE Blood Glucose Monitoring System 333 is traceable to the NIST 917b dry D-glucose reference material.

Test Strip Stability

The GE Blood Glucose Test Strips 333 remains unchanged compared to the test strips of the predicate device cleared under k092052. Only the brand name of the glucose test strip has been changed from the Rightest Blood Glucose Test Strips GS550 to the GE Blood Glucose Test Strips 333. Test strip stability was established in k092052 to support a 12 month shelf life when stored at unopened at 39°F to 86°F (4°C to 30°C) and open vial stability of 6 months when stored within the recommended storage temperature range of 39°F to 86°F (4°C to 30°C) and relative humidity of 10% to 90%.

Control Solution Value Assignment and Stability

The GE Blood Glucose Monitoring System 333 is used with the Rightest Control Solution GC550 (k092052). Stability of control solutions was established with real-time studies in k092052. Protocols and acceptance criteria were adequate to support a shelf-life of 24 months and open vial stability of 90 days when stored between 39°F to 86°F (4°C to 30°C) and tightly closed after use.

Value assignment for use of the control solutions with the Rightest GS550 blood glucose test strips is based on measurements using an appropriately calibrated established laboratory reference method (YSI 2300 analyzer calibrated with YSI 2747 calibrator solutions, NIST SRM #917b Clinical Dextrose). The values for the Control Solutions were assigned by repeat analysis using three different lots test strips and ten meters. The mean and standard deviation are used to establish the acceptable range for the strips. The range for each control solution is provided in the labeling.

d. *Detection limit:*

See linearity study

e. *Analytical specificity:*

To assess potential interference the sponsor used three test strip lots to evaluate two glucose concentration intervals (60-100 and 150-300 mg/dL) spiked with potentially interfering substances at therapeutic and toxic levels. Each sample was analyzed 5 times with 5 meters to analyze the 19 substances tested. Glucose values measured with the GE Blood Glucose Monitoring System 333 with test samples (containing potential interfering substances) were compared with values measured from control conditions (without potential interfering substances). Interference was calculated as $((Conc._{Test} - Conc._{Control})/Conc._{Control} \times 100)$, and the sponsor defined significant interference as ≤10%. Results are presented in the table below:

Potential Interfering Substance	Highest Concentration at which no significant interference was observed (mg/dL)
Acetaminophen	20
Ascorbic Acid	5
Dopamine HCl	2.5
Ibuprofen	50
L-Dopa	3
Methyl Dopa	1.5
Salicylic Acid	20
Tetracycline	1.5
Tolbutamide	100
Bilirubin-unconjugated	40
Cholesterol	600
Creatinine HCl	10
Triglycerides	3000
Uric Acid	10
Maltose	200
Xylose	40
Galactose	200
Lactose	50
Icodextrin	500

Based on these results, the sponsor has the following limitations in the labeling: High concentrations of Uric acid ≧ 10 mg/dL, Cholesterol ≧ 600 mg/dL, and Ascorbic acid (Vitamin C) ≧5 mg/dL may interfere with the glucose test causing inaccurate test results.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

To assess system accuracy of the GE Blood Glucose Monitoring System 333, healthcare professionals tested 103 capillary blood samples from the fingertip, palm, and forearm, ranging in glucose concentration from 21.9 - 591.0 mg/dL, using 2 meters and 3 lots of test strips. Results were compared to the same samples measured using an established laboratory reference method (YSI 2300 analyzer). Five samples <45mg/dL and five samples >400mg/dL were altered.

The meter results relative to reference method are summarized in the tables below:

Fingertip: System Accuracy for blood glucose concentration <75 mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
19	12/19 (63.2%)	19/19 (100.0%)	19/19 (100.0%)

Fingertip: System Accuracy for blood glucose concentration ≥75 mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
84	67/84 (79.8%)	84/84(100%)	84/84(100.0%)

Linear regression: Y=1.000X+-1.51; r = 0.998

Palm: System Accuracy for blood glucose concentration <75 mg/dL

Number of test results	Within ± 5 %	Within ± 10 %	Within ± 15 %
19	10/19 (69.6%)	19/19 (100%)	19/19(100.0%)

Palm: System Accuracy for blood glucose concentration ≥75 mg/dL

Number of test results	Within ± 5 %	Within ± 10 %	Within ± 15 %
84	59/84 (70.2%)	81/84 (99.8%)	84/84 (100.0%)

Linear regression: Y=1.010X+-2.68; r= 0.998

Forearm: System Accuracy for blood glucose concentration <75 mg/dL

Number of test results	Within ± 5 %	Within ± 10 %	Within ± 15 %
19	13/19 (68.4%)	18/19 (94.7%)	19/19 (100%)

Forearm: System Accuracy for blood glucose concentration ≥75 mg/dL

Number of test results	Within ± 5 %	Within ± 10 %	Within ± 15 %
84	50/84 (59.5%)	80/84 (95.2%)	84/84 (100.0%)

Linear regression: Y=1.006X+0.74; r = 0.993

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 study

To assess the performance of the GE Blood Glucose Monitoring System 333 in the hands of the intended users a study was conducted at clinical centers and home-environment simulated sites at 10 locations. The study participants were provided with the User's Manual in English and performed finger stick, palm and forearm tests without additional instruction or assistance. A technician collected additional samples from each participant for measurement on an established laboratory reference method (YSI 2300 analyzer). Sufficient sample volume for measurement with the reference method was obtained from 157 study participants. Three study participants failed to obtain sufficient sample volume for forearm testing. Results from participants were compared to results obtained with the reference method. The range of glucose values tested was 67.4 - 480 mg/dL. Three test strip lots were used in the study. The results are summarized below:

Lay user result vs. Reference Method

Glucose concentrations <75 mg/dL

Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 20 mg/dL
Fingertip	4/4 (100.0%)	4/4 (100.0%)	4/4 (100.0%)	4/4 (100.0%)
Palm	4/4 (100.0%)	4/4 (100.0%)	4/4 (100.0%)	4/4 (100.0%)
Forearm	3/4 (75.0%)	4/4 (100.0%)	4/4 (100.0%)	4/4 (100.0%)

Glucose concentrations ≥75 mg/dL

Glucose ≥75 mg/dL	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 20 mg/dL
Fingertip	70/153 (45.8%)	136/153 (88.9%)	151/153 (98.7%)	153/153 (100.0%)
Palm	76/153 (49.7%)	131/153 (85.6%)	153/153 (100.0%)	153/153 (100.0%)
Forearm	78/150 (52.0%)	123/150 (82.0%)	147/153 (98.0%)	147/150 (98.0.0%)

Linear regression analysis:

Layperson	fingertip vs. reference -plasma	palm vs. reference -plasma	forearm vs. reference -plasma
Test number (n)	157	157	154
Slope	1.01	1.00	1.00
Intercept	-0.19	2.02	-0.89
r	0.99	0.99	0.99

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

Reference:

American Diabetes Association: Diabetes Care, January 2015, volume 38 (Suppl. 1) S8-S16.

N. Instrument Name:

GE Blood Glucose Meter 333

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 _X_____ or No _____

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.

   The meter automatically distinguishes control solution from blood and marks control solution tests with a check "cs" icon and excludes them from average calculations.

   The GE Blood Glucose Monitoring Meter 333 memory stores up to 500-blood glucose test results (including control solution results) with the date and time.

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 for the blood glucose meter by the user. The meter is automatically coded.

6. Quality Control:

   Two levels of aqueous glucose control solutions are available with this system, Level 2 and Level 4. These solutions are available for purchase separately. 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 bottle 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. Sample volume Study:
   The GE Blood Glucose Monitoring System 333was tested with venous blood at three glucose concentration intervals (40-60, 80-120, and 300-330 mg/dL) and nine specimen volumes. For each glucose interval, the specimen volumes were adjusted to 0.60, 0.65, 0.70, 0.75, 0.80, 1.00, 1.25, 2.00, and 3.00 µL. Each sample was measured in three replicates for each of the three strips and the same sample was also measured by an established laboratory reference method (YSI 2300 analyzer)). The bias for above replicates in each test strip lot calculated. Results support the claimed minimum sample volume of 0.75 µL.

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 50-75, 80-120, and 270-330 mg/dL. The samples were tested at 0, 1000, 2000, and 3275 m sea level. Results obtained were compared with those obtained with an established laboratory reference method (YSI 2300 analyzer). The results demonstrate acceptable bias relative to the reference 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 GE Blood Glucose Monitoring System 333was tested with venous blood at six glucose concentration intervals (20-50, 60-80, 135-165, 180-220, 270-330, and 360-440) and nine hematocrit levels. For each glucose concentration interval, the hematocrit levels were adjusted to 10, 20, 25, 30, 40, 55, 60, 65, and 70%. Each sample was measured in five replicates for each of the three test strip lots and the same sample was also measured with an established laboratory reference method (YSI 2300 analyzer). Results from this study support the sponsor's claim that hematocrit in the range of 20-60% does not interfere with glucose measurements.

4. Test System Operating Conditions:
   The GE Blood Glucose Monitoring System 333 was evaluated using three meters under three different temperatures 50-52 °F (10-11°C), 77 ±2°F (25±2 °C) and102-104 °F (39-40 °C) at two levels of relative humidity (10±5% and 90±5%) with glucose control solutions at 3 levels. Each sample was tested in 5 replicates. The results were compared against an established laboratory reference method (YSI 2300 analyzer). Results support claims in the labeling that the GE Blood Glucose Monitoring System 333 can be used in conditions of 50 to 104°F (6 to 44°C) with relative humidity of 10 to 90%.

5. Readability Assessment:
   The readability of the labeling (user's manual, getting started guide, instructions for use and blood glucose test strip insert) using Flesch-Kincaid analysis were found to be written at the 8th grade level. During the lay users study the participants were asked to complete a questionnaire to evaluate the ease of use of the device and the clarity of the English language labeling. Overall, the users indicated they could successfully perform the test and the user manual was clearly written.

6. Infection Control:
   The device is intended for a single-patient use only. The studies were performed to validate the virucidal efficacy of disinfectant used to clean and disinfect the two external materials on the exterior surface of the blood glucose meter against Hepatitis B. Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter. The robustness studies were designed to simulate disinfection procedures 8 times a month and approximately 520 times in a meter's five-year lifetime.

7. Customer Support Center available Monday through Friday 8:00 am to 5:00 pm (PST) by calling 1-866-613-7085.

8. Software validation:
   Software validation and verification has been reviewed and the information provided was deemed to be adequate.

9. EMC Testing:
   The sponsor provided appropriate documentation certifying that electromagnetic testing (EMC) has been performed and the GE Blood Glucose Monitoring System 333 was found to be compliant.

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.