

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

A. 510(k) Number:

k110737

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative Amperometric assay (FAD-Glucose Dehydrogenase)

E. Applicant:

Bionime Corporation

F. Proprietary and Established Names:

Rightest Glucose Monitoring System GM700

G. Regulatory Information:

1. Regulation section:
21 CFR 862.1345, Glucose test system
21 CFR 862.1660, Quality Control Material (assayed and unassayed)
2. Classification:
Class II, Class I (reserved)
3. Product code:
NBW, System, Test, Blood Glucose, Over The Counter
LFR, Glucose Dehydrogenase, Glucose
JJX, Quality Control Material (Assayed and Unassayed)
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Rightest Blood Glucose Monitoring System GM700 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole samples drawn from the fingertips, palm and forearm. The Rightest Blood Glucose Monitoring System GM700 is intended to be used by a single person and should not be shared.

The Rightest Blood Glucose Monitoring System GM700 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 Rightest Blood Glucose Monitoring System GM700 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 Rightest Blood Glucose Test Strip GS700 is for use with the Rightest Blood Glucose meter GM700 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm or forearm.

The Rightest Control Solution GC700 is for use with the Rightest Blood Glucose meter GM700 and Rightest Blood Glucose Test Strips GS700 to check that the meters and test strip are working together properly and that the test is performing correctly.

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
- For single-patient use only
- Alternative site testing (AST) testing should only be done during steady-state times (when glucose is not changing rapidly).
- AST should not be used to calibrate continuous glucose monitors (CGMs).
- AST should not be used for insulin dose calculations.

4. Special instrument requirements:

Rightest Blood Glucose Meter GM700

I. Device Description:

The Rightest Blood Glucose Monitoring System Model GM700 consists of a the Rightest GM700 Blood Glucose meter, Rightest Auto Code Key (combined on the meter), the Rightest Blood Glucose Test Strips GS700 (sold separately), five levels of Control Solutions (L1, L2, L3, L4, L5; sold separately), Rightest GD500 Lancing Device for single patient use only and lancets, clear cap (sold separately), carry case, and User Manual.

Each test strip contains the following reagent compositions: flavin adenine dinucleotide-glucose dehydrogenase (9.0% FAD-GDH from *Aspergillus Oryzae*); potassium ferricyanide (53.7%); and other non-reactive ingredients.

Each box of control solutions contains one vial (4.0 mL) of each aqueous control solution, each: Level 1 (40-50 mg/dL), Level 2 (120 to 150 mg/dL), Level 3 (220 to 230 mg/dL), Level 4 (330 to 360 mg/dL), Level 5 (450 to 500 mg/dL).

J. Substantial Equivalence Information:

1. Predicate device name(s):

Rightest Blood Glucose Monitoring System Model GM550; Bionime Corporation

2. Predicate K number(s):

k092052

3. Comparison with predicate:

Similarities and Differences of the Blood Glucose System		
Item	Predicate Device Rightest Blood Glucose Monitoring System, Model GM550 (k092052)	Candidate Device Rightest Blood Glucose Monitoring System GM700
Intended Use/Indications for Use	It is intended to be used for quantitative measurement of glucose in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Setting	At home and in a clinical settings	Only for single patient use at home
Detection method	Amperometry	Same
Enzyme	Glucose Oxidase	FAD-Glucose Dehydrogenase
Calibration Coding	Auto code	Smart Auto Code
Memory	500 control and glucose (1, 7, 14, 30, 90 day average)	1000 with date and time (1, 7, 14, 30, 60, 90 day average)
Test range	20 - 600 mg/dL	Same
Hematocrit range	30 - 60%	30-55%
Sample type	Capillary whole blood	Same
Sample sites	Fingertip, forearm, palm	Same
Sample volume	1 µL	Same
Sample test time	5 seconds	Same

Similarities and Differences of the control solution		
Item	Predicate Device Rightest Control Solutions GC550 (k092052)	Candidate Device Rightest Control Solutions GC700
Intended use/Indications for Use	To check that the glucose meter and test strips are working together properly	Same
Matrix	Viscosity-adjusted, aqueous liquid	Same
Number of levels	Normal and High	5 levels (Level 1, Level 2, Level 3, Level 4, Level 5)

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 14971:2007, Medical devices – Application of risk management to medical devices.
- CLSI EP7-A2, Interference Testing in Clinical Chemistry; Approved Guideline.
- 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.

L. Test Principle:

The Rightest Blood Glucose Monitoring System, Model GM700 uses electrochemical methodologies. The system quantitatively measures blood glucose levels using an amperometric method. The system employs flavin adenine dinucleotide-glucose dehydrogenase (GDH-FAD) enzyme chemistry. The electrons generated during this reaction are transferred from the blood to the electrodes. The magnitude of the resultant current is proportional to the concentration of glucose in the specimen and the signal is converted into a readout 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 whole blood samples spiked with five different glucose concentrations (30 to 50, 51 to 110, 111 to 150, 151 to 250, 251 to 400). Each glucose level was analyzed in replicates of 10, with 3 test strip lots, and 10 meters for a total of 300 tests per each glucose level for each meter. Results are summarized below:

Within-run precision for glucose:

Glucose Level (mg/dL)	Number of tests	Mean (mg/dL)	SD (mg/dL)	CV (%)
30 to 50	300	42.8	1.3	2.97
51 to 110	300	80.1	2.0	2.46
111 to 150	300	132.6	2.6	1.93
151 to 250	300	196.3	3.7	1.88
251 to 400	300	335.8	5.3	1.57

Between-day precision was evaluated using five levels of glucose control solutions with concentrations (39 to 59, 107 to 145, 201 to 273, 300 to 406, and 418 to 566 mg/dL). Each sample was measured in duplicate with three test strip lots and 10 Rightest GM700 meters. These tests were performed over 20 days, for a total of 400 tests per glucose level. Results are summarized below.

Between-day precision for glucose:

Glucose Level (mg/dL)	Number of tests	Mean (mg/dL)	SD (mg/dL)	% CV
39 to 59	300	49.3	1.5	2.97
107 to 145	300	127.2	2.9	2.31
201 to 273	300	237.5	4.3	1.82
300 to 406	300	354.5	7.0	1.97
418 to 566	300	496.3	8.6	1.74

b. *Linearity/assay reportable range:*

Linearity was evaluated using three test strip lots and 15 mixed pools of venous blood samples ranging in glucose concentrations (as measured by YSI) of 3, 10, 23, 44, 92.0, 148, 190, 252, 292, 356, 391, 447, 526, 571, 620 mg/dL for test strip lots #2 and #3 and 1, 14, 21, 42, 99, 154, 216, 255, 313, 353, 405, 443, 522, 594, 641 mg/dL for test strip lot #1. Each level was measured in triplicate with each of 3 test strip lots and the values from the Rightest GM700 meter were compared with those obtained from YSI-2300. Results from regression analysis:

$$\text{Test strip lot \#1: } y = 0.9882x + 0.5809; R^2 = 0.9994$$

$$\text{Test strip lot \#2: } y = 0.9932x + 0.6005; R^2 = 0.9986$$

$$\text{Test strip lot \#3: } y = 0.9912x + 2.8143; R^2 = 0.9990$$

The results of the study support the sponsor's claimed glucose measurement range of 20-600 mg/dL.

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

Traceability:

The Rightest Blood Glucose Monitoring System GM700 is traceable to the NIST SRM 917b reference material. The method comparison study was performed using the candidate device and YSI as the reference method (see Section 2.a.)

Test Strip Stability:

Test strip stability was assessed in accelerated and real time studies. Testing protocols and acceptance criteria for the Rightest Blood Glucose Test Strips GS700 were reviewed and found to be acceptable. The manufacturer claims shelf life stability of 18 months and an open-vial stability of 4 months at the recommended storage temperatures of 39°F-86°F.

Control Solution Value Assignment and Stability:

Value assignment: Five levels of aqueous control solutions (levels 1 to 5) are available for use with the Rightest GM700 test system. Value assignment for use of the control solutions with the Rightest GS700 glucose test strips is based on measurements using the YSI 2300. The values for each of the control solutions are assigned by repeat analysis using Rightest GM700 test strips and ten Rightest GM700 meters. The mean, SD and CV are used to establish the ranges for each control solution which are provided on the test strip vial label.

Stability Testing: Stability was assessed using real-time and accelerated testing for each control solution level. Protocols and acceptance criteria were reviewed and found to be acceptable to support the shelf life stability claim of 16 months and an open-vial stability claim of 3 months when stored at the recommended storage temperatures of 36°F to 86°F.

d. *Detection limit:*

See linearity study in Section M1b above.

e. *Analytical specificity:*

Interference studies were performed by spiking venous blood with two levels of glucose concentrations (60 to 100 and 150 to 300 mg/dL). Each of these samples was divided into a test pool and a control pool and each of 18 potential endogenous and exogenous interfering substances was added to the test pool. Each compound was tested at two concentrations, normal/therapeutic and high/toxic concentrations.

Each sample was analyzed 5 times with the Rightest GM700 meter and the % difference between the interferent containing sample and the control sample calculated. The sponsor defines no significant interference as $\leq 10\%$

difference relative to the control sample. Results are presented in the table below:

Potential Interfering Substance	Concentration with no Significant Interference (mg/dL)	Potential Interfering Substance	Concentration with no Significant Interference (mg/dL)
Acetaminophen	20	Salicylic Acid	20
Ascorbic Acid	6	Tetracycline	1.5
Bilirubin	40	Tolbutamide	100
Cholesterol	500	Triglycerides	1700
Creatinine	10	Uric Acid	10
Dopamine	2.5	Maltose	200
Ibuprofen	50	Galactose	50
L-Dopa	3.0	Lactose	50
Methyldopa	1.5	Xylose	10

The sponsor has the following limitations in their labeling: Xylose concentrations ≥ 10 mg/dL and Uric acid ≥ 10 mg/dL may interfere with the test resulting in inaccurate test results.

f. *Assay cut-off:*

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

System Accuracy:

To assess system accuracy, results from the Rightest GM700 Blood Glucose Monitoring System were compared to a reference method, YSI 2300. Capillary samples from 109 participants with glucose concentrations ranging from 22.3 to 500 mg/dL were tested using three test strip lots. To obtain extreme blood glucose concentrations some samples were altered. The results relative to YSI are summarized in the tables below:

For glucose concentrations <75 mg/dL

Site	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Finger	14/20 (70%)	19/20 (95.0%)	20/20 (100%)
Palm	12/20 (60%)	19/20 (95.0%)	20/20 (100%)
Forearm	14/20 (70%)	19/20 (95.0%)	20/20 (100%)

For glucose concentrations ≥ 75 mg/dL

Site	Within $\pm 5\%$	within $\pm 10\%$	within $\pm 15\%$	within $\pm 20\%$
Finger	60/89 (67.4%)	78/89 (87.6%)	89/89 (100%)	89/89 (100%)
Palm	47/89 (52.8%)	79/89 (88.8%)	89/89 (100%)	89/89 (100%)
Forearm	36/89 (40.4%)	69/89 (77.5%)	89/89 (100%)	89/89 (100%)

Linear Regression Analysis:

Comparison vs. YSI	Test strip lot	Range of values	Slope and y-intercept	R
Finger	1	28-526	$y=0.973x+4.07$	0.995
	2	23-522	$y=0.980x+0.97$	0.994
	3	27-551	$y=1.018x-0.94$	0.994
Palm	1	29-519	$y=0.996x+1.36$	0.992
	2	25-531	$y=0.990x-0.26$	0.993
	3	28-554	$y=1.039x-2.67$	0.994
Forearm	1	27-518	$y=0.965x+0.72$	0.991
	2	25-529	$y=0.978x-1.87$	0.992
	3	26-555	$y=1.020x-5.47$	0.991

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 Rightest GM700 Blood Glucose Monitoring System in the hands of the intended users the sponsor performed a study with 167 lay user participants, who collected 167 each of fingerstick and palm samples and 163 forearm samples, at three study locations with three test strip lots. Results were analyzed by comparing blood glucose results from the

Rightest GM700 meter obtained by the lay user against the YSI 2300 reference value. The samples ranged from 56 to 403 mg/dL as measured by YSI. The results are summarized in the tables below:

Lay-user vs. YSI:

For glucose concentrations <75 mg/dL

Site	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Finger	4/5 (80%)	5/5 (100%)	5/5 (100%)
Palm	1/5 (20%)	3/5 (60%)	5/5 (100%)
Forearm	2/5 (40%)	5/5 (100%)	5/5 (100%)

For glucose concentrations ≥ 75 mg/dL

Site	Within ± 5 %	within ± 10 %	within ± 15 %	Within ± 20 %
Finger	70/162 (43.2%)	125/162 (77.2%)	154/162 (95.1%)	160/162 (98.8%)
Palm	81/162 (50.0%)	127/162 (78.4%)	155/162 (95.7%)	162/162 (100%)
Forearm	51/158 (32.3%)	102/158 (64.6%)	138/158 (87.3%)	152/158 (96.2%)

Linear Regression Analysis:

Comparison	Slope and y-intercept	r
Finger vs. YSI	$y=0.95x+2.09$	0.97
Palm vs. YSI	$y=1.06x-9.48$	0.98
Forearm vs. YSI	$y=1.00x-5.70$	0.98

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Expected glucose values without diabetes:

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

American Diabetes Association: Standard of Medical Care in Diabetes 2011, Diabetes Care, vol.34, supplement 1, S11-S61, January 2011.

N. Instrument Name:

Rightest Blood Glucose Meter GM700

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and requires a sample volume of 1.0 μ L.

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

Yes _____ or No X .

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 this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

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

5. Calibration:

The meter has a "Smart Auto Code Key" that is installed into the meter and contains the test strip port. The code key identifies the test strip code automatically; therefore, no coding is required by the user. The labeling includes instructions for the user to contact customer service if the Code Error symbol appears on the meter. The code key is replaceable, but only by an authorized Bionime representative.

6. Quality Control:

Five levels of aqueous glucose control solutions are available with this system. Control solution Level 2 is provided with the kit. The meter has a function for the

user to select the level of control solution they wish to run to prevent control results from being stored in the internal memory as patient results. Recommendations on when to test the control materials are provided in the labeling. The control solution readings are not included in the average of the patient results when the measurements are performed in the “CS measurement mode”. 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 Rightest GM700 Blood Glucose Monitoring System was evaluated using venous whole blood samples with hematocrit levels 20, 25, 30, 40, 55, 60 and 65% spiked with glucose to achieve 6 concentrations ranging from 40 to 400 mg/dL (20 to 50, 60 to 80, 135 to 165, 180 to 220, 270 to 330, 360 to 440 mg/dL). Each sample was then tested 9 times using the Rightest GM700 glucose meter and the values were compared with those obtained from YSI-2300 analyzer. The % biases relative to YSI were acceptable within the claimed hematocrit range of 30 to 55%.
- 2) Altitude study: Venous whole blood samples collected from 5 volunteers and adjusted to obtain 3 glucose concentration ranges (30 to 50, 80 to 120, 240 to 360 mg/dL) were tested at 0, 3280, 6562, and 10,745 feet (0, 1000, 2000, 3275 meters) above sea level. Results were compared to YSI values. The results demonstrate acceptable bias to YSI to support the claims in the labeling that altitudes up to 10,000 feet (3048 meters) have no significant effect on blood glucose measurements from the Rightest GM700 glucose meter.
- 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 Rightest GM700 system. Blood samples were tested at six sample volumes (0.6, 0.65, 0.75, 0.8, 1.0 and 1.25 μ L) and values obtained were compared to YSI values. Results support the claimed sample volume of 1.0 μ L 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 6.3°C to 43.6°C and relative humidity from 11% to 92%. Meter results were compared to YSI values. Six temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, average temperature/low humidity, average temperature/high humidity, high temperature/low humidity, and high temperature/high humidity. No significant effect (relative to YSI) 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 43 to 111°F (6 to 44°C) with relative humidity of 10 to 90%.

- 5) Infection Control Studies: The device is intended for single-patient use only. Discide Ultra disinfecting towelettes with EPA registration #10492-4 were validated demonstrating complete inactivation of live virus for use with the meter and lancing device. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter and lancing device after 550 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate 5 years of meter and lancing device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.
- 6) EMC testing was evaluated and certified by SGS Taiwan LTD. and Verification of Compliance certificates provided.
- 7) 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 8th grade level.
- 8) Customer service is available Monday through Friday 8:00 am to 5:00 pm PST by calling 1-888-481-8485.

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.