Food and Drug Administration
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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

k190564

B Applicant

Bionime Corporation

C Proprietary and Established Names

Rightest Blood Glucose Monitoring System GM700S
Rightest Blood Glucose Monitoring System GM700SB

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New devices

B Measurand:

Glucose in capillary whole blood obtained from the fingertip, forearm, or palm.

C Type of Test:

Quantitative, amperometric method, glucose dehydrogenase (GDH-FAD)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

Rightest Blood Glucose Monitoring System GM700S
The Rightest Blood Glucose Monitoring System GM700S consists of the Rightest Blood Glucose Monitoring Meter GM700S and the Rightest Blood Glucose Test Strips GS700. The Rightest Blood Glucose Monitoring System GM700S 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 Rightest Blood Glucose Monitoring System GM700S is intended for self-testing outside the body (in-vitro diagnostic use), by individuals with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended to be used by a single person and should not be shared. The systems 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).

Rightest Blood Glucose Monitoring System GM700SB
The Rightest Blood Glucose Monitoring System GM700SB consists of the Rightest Blood Glucose Monitoring Meter GM700SB and the Rightest Blood Glucose Test Strips GS700. The Rightest Blood Glucose Monitoring System GM700SB 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 Rightest Blood Glucose Monitoring System GM700SB is intended for self-testing outside the body (in-vitro diagnostic use), by individuals with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended to be used by a single person and should not be shared. The systems 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).

C Special Conditions for Use Statement(s):

- For over-the-counter use
- Not for neonatal use.
- For single patient use at home by a lay user. The single-patient use system should not be shared.
- Inaccurate test results may be obtained at altitudes greater than 10,000 feet (3048 meters) above sea level.
- Severe dehydration and excessive water loss may cause inaccurately low results.
- Not for screening or diagnosis of diabetes mellitus.
- This system should not be used in people who are critically ill, in shock, or persons in a hypotensive or hyper-osmolar state.
- Do not test the blood sample from palm or forearm when glucose is changing rapidly (scenarios: after drinking, after meal, after exercise).

- Do not use results from the palm or forearm to calibrate continuous glucose monitoring systems (CGMS), or for insulin dose calculations.
- The blood sample from palm or forearm should not be tested when testing for hypoglycemia (low blood glucose).
- This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

D Special Instrument Requirements:

Rightest Blood Glucose Meter GM700S
Rightest Blood Glucose Meter GM700SB

IV Device/System Characteristics:

A Device Description:

The two systems in this submission, the Rightest Blood Glucose Monitoring System GM700S and the Rightest Blood Glucose Monitoring System GM700SB, consist of the following components:

- Rightest Blood Glucose Meter (GM700S or GM700SB)
- Rightest Blood Glucose Test Strips GS700
- Rightest Control Solution GC700 (Level 1, Level 2, Level 4)

Both systems employ the same device technology. The only difference between the Rightest Blood Glucose Monitoring System GM700S and the Rightest Blood Glucose Monitoring System GM700SB is the presence of Bluetooth in the Rightest Blood Glucose Monitoring System GM700SB.

B Principle of Operation:

The Rightest Blood Glucose Monitoring System GM700S and Rightest Blood Glucose Monitoring System GM700SB quantitatively measure blood glucose levels using amperometric technology. The system employs flavin adenine dinucleotide-glucose dehydrogenase (GDH-FAD) enzyme chemistry. Whole blood applied to a test strip initiates a reaction where electrons are transferred from the blood to the electrodes. The magnitude of the resultant current is proportional to the concentration of glucose in the sample. The detected current signal is then calculated by the meter and glucose concentration reading is then displayed on the meter display. The meter is calibrated to display plasma-equivalent concentration results.

C Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☒	☐
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:

   Rightest Blood Glucose Meter GM700S
   Rightest Blood Glucose Meter GM700SB

2. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

3. Specimen Sampling and Handling:

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

4. Calibration:

   Calibration is automatic. There is no user input needed for calibration or coding.

5. Quality Control:

   Control Solutions are aqueous solutions containing glucose and are available at three levels. Instructions on how to order the control solutions are included in the user manual. An acceptable range for each control level is printed on the test strip vial label. The user is instructed to perform control solution testing at least once per week and cautioned not to use the meter if the control result falls outside these ranges. Control solution test results are not averaged with blood glucose results when the CS measurement mode is used.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Rightest Blood Glucose Monitoring System GM720

B Predicate 510(k) Number(s):

k140210

C Comparison with Predicate(s):

Device & Predicate Device(s):	K190564	K140210
Device Trade Name	- Rightest Blood Glucose Monitoring System GM700S -Rightest Blood Glucose Monitoring System GM700SB	Rightest Blood Glucose Monitoring System GM720
General Device Characteristic Similarities		
Intended Use/Indications For Use	Quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip as an aid to monitor the effectiveness of diabetes control	Same
Sample Source	Capillary whole blood from AST (alternative site testing) and finger	Same
Measuring Range	20-600 mg/dL	Same
Sample Volume	0.75 µL	Same
Detection Method	Amperometry	Same
Enzyme	FAD Glucose Dehydrogenase	Same
General Device Characteristic Differences		
Hematocrit	20-60%	20-65%
Bluetooth Capability	Rightest Blood Glucose Monitoring System GM700SB	None

VI Standards/Guidance Documents Referenced:

- Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use, Guidance for Industry and Food and Drug Administration Staff. October 11, 2016.

- IEC 61010-1, Edition 3.0: 2010, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General Requirements.
- IEC 60601-1-2, Edition 3.0: 2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- ISO 14971:2007, Medical Devices - Application of risk management to medical devices
- CLSI EP07-A2, Interferences Testing in Clinical Chemistry; Approved Guideline - Second Edition.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

Unless otherwise noted, the analytical studies detailed below were performed with the Rightest Blood Glucose Monitoring System GM700SB, which is identical the Rightest Blood Glucose Monitoring System GM700S with the exception of the presence of Bluetooth. Therefore, the analytical studies performed with the Rightest Blood Glucose Monitoring System GM700SB are representative of the performance for both systems in this 510(k) submission.

1. Precision/Reproducibility:

Repeatability (within-run precision):
The sponsor performed repeatability (within-day) precision studies using venous whole blood adjusted to 5 different glucose concentration levels (30 to 50, 51 to 110, 111 to 150, 151 to 250, and 251 to 400 mg/dL). Each glucose concentration level was analyzed in replicates of 10, with 5 test strip lots, and 10 meters, for a total of 500 tests per glucose level. Results are summarized below:

Glucose Level (mg/dL)	n	Average Glucose (mg/dL)	SD (mg/dL)	CV (%)
30-50	500	42	3.3	7.8
51-110	500	101	4.1	4.1
111-150	500	131	4.5	3.4
151-250	500	198	4.4	2.2
251-400	500	370	8.8	2.4

Intermediate Precision:
Intermediate (day-to-day) precision was evaluated using 3 levels of glucose control solutions over 10 days with 5 test strip lots. For each level, on each day, 10 meters were used, with 1 replicate collected per meter for a total of 10 replicates per day for each glucose level. Results are summarized below:

Glucose Level	n	Average Glucose (mg/dL)	SD (mg/dL)	CV (%)
1	500	51	3.5	6.9
2	500	110	4.5	4.0
3	500	255	10.2	4.0

2. Linearity:

Linearity was evaluated using fourteen venous whole blood samples with glucose concentrations of 15.5, 24.0, 56.6, 89.8, 154.5, 201.5, 266.0, 312.5, 356.5, 422.0, 474.5, 512.0, 576.0, and 630.5 mg/dL as measured by the comparator method, YSI 2300. Each sample was tested with 3 test strip lots. For each lot, 3 measurements with 3 meters were taken per glucose level. The linear regression results are presented below:

Lot 1: $y = 0.9936x – 1.3391$; $R^2=0.9994$
Lot 2: $y = 0.9771x – 1.4742$; $R^2=0.9998$
Lot 3: $y = 0.9814x + 0.2001$; $R^2=0.9992$

The results of the linearity study support the claimed glucose measurement range of 20-600 mg/dL. If a sample is less than 20 mg/dL or greater than 600 mg/dL an error message is returned to the user. The error messages were validated using blood glucose samples outside the measuring range of the device and demonstrated that the error messages function as intended.

3. Analytical Specificity/Interference:

To assess potential interferences, the sponsor used venous whole blood samples adjusted to glucose concentrations between 75 and 350 mg/dL. Each sample was divided into a test pool and a control pool, with the potential interfering substance added to the test pool. The difference between the test sample and the control sample was calculated using mean of 10 replicates per each of 3 test strip lots. The compounds at the concentrations listed below did not have significant interference (defined by the sponsor as average bias between spiked and control sample glucose results within ± 10% for glucose >100 mg/dL and within ± 10 mg/dL for glucose <100 mg/dL). The highest concentrations at which no significant interference was observed are presented in the following table:

Substance	Highest Concentration tested with no observed significant interference
Acetaminophen	20 mg/dL
Ascorbic Acid	3 mg/dL
Bilirubin (unconjugated)	50 mg/dL
Bilirubin (conjugated)	50 mg/dL
Cholesterol	700 mg/dL
Creatinine	10 mg/dL
Dopamine	1.25 mg/dL
Galactose	200 mg/dL
Gentisic acid	7.5 mg/dL
Glutathione (reduced)	60 mg/dL
Hemoglobin	6000 mg/dL
Ibuprofen	50 mg/dL
L-Dopa	2 mg/dL
Maltose	480 mg/dL
Methyldopa	1.5 mg/dL

Salicylic acid	60 mg/dL
Sodium Chloride	1052 mg/dL
Tolazamide	15 mg/dL
Tolbutamide	64 mg/dL
Triglycerides	3000 mg/dL
Uric Acid	10 mg/dL
Xylose	10 mg/dL
Icodextrin	1100 mg/dL
Lactose	50 mg/dL
Tetracycline	1.5 mg/dL
Pralidoxime iodide (PAM)	4 mg/dL

The following limitations are listed in the User Manual and the Test Strip Insert:

- The meter result may not be correct if you are taking vitamin C more than recommended daily intake (Ascorbic Acid blood concentration ≧ 3 mg/dL).
- If you have a condition that may cause your blood levels of Uric Acid to increase (Uric Acid blood concentration ≧ 10 mg/dL), such as kidney disease or gout, then the results from your meter may not be correct.
- If you undergo a Xylose Absorption test, your blood glucose results may be not reliable following the test. You should not use the Rightest Blood Glucose Monitoring System following Xylose Absorption tests. If you are unsure, then ask your healthcare professional.

4. Assay Reportable Range:

   The reportable range for each system is 20 to 600 mg/dL supported by the linearity assay study above (Section A.2).

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   The system is traceable to NIST SRM #917b glucose reference material. A method comparison was performed using the candidate device and YSI 2300 as the comparator method. The meter provides plasma-equivalent results.

   Test Strip Stability:

   Test strip stability was assessed using accelerated and real time stability studies. Protocols and acceptance criteria were reviewed and found acceptable. The labeling includes claims that the Rightest Blood Glucose Test Strips GS700 are stable for 4 months after opening and 24 months unopened when stored between 4℃ to 30℃ (39 to 86℉) and 10-90% relative humidity.

6. Detection Limit:

The reportable range for each system is 20 to 600 mg/dL supported by the linearity assay study above (Section A.2).

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   Not applicable.

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable. See section C.3 below for performance in the hands of the intended user.

2. Matrix Comparison:

   Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   To assess the performance of the Rightest Blood Glucose Monitoring Systems in the hands of the intended users, the sponsor performed a study with 354 lay user participants. The Rightest Blood Glucose Monitoring System GM700SB was used as a representative meter as it contains all available user features (see "Device Description" for description of the differences between meters). The users were responsible for obtaining their own capillary sample and performing a blood glucose test using only the instructions from the product labeling. A total 6 test strip lots were used in the study. Results were analyzed by comparing the blood glucose results obtained by the lay users against results obtained with a laboratory-based comparator method (YSI 2300 analyzer). The glucose concentrations in the samples ranged from 63.7-488 mg/dL, which includes 24 native samples < 80 mg/dL and 33 samples > 250 mg/dL as measured by the YSI 2300. The results are summarized below:

Fingertip

For glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
10/14 (71.4%)	14/14 (100.0%)	14/14 (100.0%)

For glucose concentrations ≥ 75 mg/dL:

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
211/340 (62.1%)	317/340 (93.2.0%)	335/340 (98.5%)	337/340 (99.1%)

Combined glucose concentrations across the measuring range:

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
220/354 (62.1%)	330/354 (93.2%)	349/354 (98.6%)	351/354 (99.2%)

Results of Linear Regression Analysis:

$y = 1.01x – 0.31$, $R^2 = 0.99$

Palm:

For glucose concentrations < 75 mg/dL:

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
10/14 (71.4%)	13/14 (92.9%)	14/14 (100.0%)

For glucose concentrations ≥ 75 mg/dL:

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
200/340 (58.8%)	302/340 (88.8%)	335/340 (98.5%)	337/340 (99.1%)

Combined glucose concentrations across the measuring range:

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
210/353 (59.4%)	314/353 (88.9%)	348/353 (98.6%)	351/353 (99.4%)

Results of Linear Regression Analysis:

$y = 0.99x + 1.69$, $R^2 = 0.99$

Forearm

For glucose concentrations < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
6/14 (42.9%)	13/14 (92.9%)	14/14 (100.0%)

For glucose concentrations ≥ 75 mg/dL:

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
156/338 (46.2%)	286/338 (84.6%)	333/338 (98.5%)	337/338 (99.7%)

Combined glucose concentrations across the measuring range:

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
160/352 (45.5%)	298/352 (84.7%)	347/352 (98.6%)	351/352 (99.7%)

Results of Linear Regression Analysis:

$y = 1.04x - 4.83$, $R^2 = 0.99$

Accuracy at Extreme Glucose Study:

To assess performance at extreme glucose concentrations, a study was conducted using blood from 102 study participants where blood was either glycolyzed to lower glucose concentrations or spiked to raise glucose concentration. Three test strip lots were used and the results were compared to the YSI 2300 comparator method. The concentrations tested ranged from 22.0-79.6 mg/dL and from 251-595 mg/dL as measured by the comparator method, YSI 2300.

For glucose concentrations < 80 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ±20%
24/51 (47.1%)	40/51 (78.4%)	49/51 (96.1%)	51/51 (100%)

For glucose concentrations > 250 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
31/51 (60.8%)	47/51 (92.2%)	51/51 (100%)	51/51 (100%)

Usability/Readability:

The lay user study participants were asked to complete a usability questionnaire regarding ease of understanding of information in the user manual and the ease of use when performing a blood glucose test. The study demonstrated that users of the device were able to understand and follow the instructions provided in the labeling to perform tasks involved in blood glucose testing.

Flesch-Kincaid readability assessment was conducted on all labeling and demonstrated that the user manuals are written at an 8th grade level or below.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The sponsor includes the following expected glucose values for people without diabetes in the device labeling:

Time of Day	Glucose Range
Fasting and before meals	<100 mg/dL
2 hours after meals	<140 mg/dL

Source: American Diabetes Association (Standards of Medical Care in Diabetes – 2018. Diabetes Care, January 2018, vol. 41, Supplement 1, S13-S27).

F Other Supportive Instrument Performance Characteristics Data:

1. Hematocrit Study:
   To evaluate the effect of hematocrit, venous blood samples with hematocrit levels of 10%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, and 70% were tested at six glucose levels (20-50, 60-80, 135-165, 180-220, 270-330, and 260-440 mg/dL). Each sample was tested in replicates of 5 test strips per strip lot, with a total of 3 lots of tests strips tested. Results from the meter were compared to results obtained using a laboratory-based comparator method (YSI 2300). The evaluation of bias relative to the comparator method demonstrated acceptable performance to support the claimed hematocrit range of 20-60%.

2. Altitude Study:
   To evaluate the effect of altitude, meters were tested at approximately sea level, 3,280, 6,560, and 10,744 feet above sea level. The evaluation tested 3 levels of glucose (50-75, 80-120, and 270-330 mg/dL) included 3 test strip lots. Results at each altitude were compared to the comparator method, YSI 2300. Results demonstrated that altitudes up to 10,744 feet above sea level have no significant effect on blood glucose measurements.

3. Sample Volume Study:
   The sponsor performed a study to support the claimed minimum sample volume. Venous whole blood samples were tested at 0.60, 0.65, 0.70, 0.75, 0.80, 1.0, 1.25, 2.0 and 3.0 µL at 3 glucose levels (50-75, 80-120, and 270-330 mg/dL) as established by the YSI 2300 comparator method. Each sample was tested in triplicate on three meters using 3 test strip lots. Results support the claimed minimum sample volume of 0.75 µL. Blood volumes below 0.75 µL resulted in an accurate result or an insufficient sample volume error message.

4. Operating Conditions Study:
   The sponsor performed temperature and humidity studies using venous blood samples with glucose samples of approximately 90 and 250 mg/dL. Temperatures ranging from 43°F - 111°F (6-44°C) and relative humidity from 10% to 90% were tested. Meter results were compared to the YSI 2300 comparator method. Four temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, high temperature/low humidity and high temperature/high humidity. The results support the claims in the labeling that the system can be used in conditions of 43°F - 111°F (6-44°C) with relative humidity of 10 to 90%.

5. Flex Studies:
   Intermittent sampling, sample perturbation, testing with used test strips, drop/shock testing, and vibration testing was completed. The testing performed demonstrated that the device is robust to intermittent sampling, sample perturbation, drop/shock, and vibration, and that an error message is returned to the user if a used test strip is inserted into the meter.

6. EMC Testing:
   The sponsor provided appropriate documentation certifying that acceptable electromagnetic testing (EMC) had been performed and that they were compliant.

7. Infection Control Studies:
   The two systems in this submission are intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meters by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, CaviWipes (EPA Registration # 46781-8). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 550 cleanings and disinfection cycles with the CaviWipes. The robustness studies were designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

8. Test Strip Lot Release Protocol:
   The test strip lot release protocol and acceptance criteria were reviewed and found to be acceptable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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