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

A. 510(k) Number:

k173638

B. Purpose for Submission:

New device

C. Measurand:

Fresh capillary whole blood glucose from fingertip, forearm or palm

D. Type of Test:

Quantitative Amperometric assay (FAD-Glucose Dehydrogenase)

E. Applicant:

Bionime Corporation

F. Proprietary and Established Names:

Rightest Blood Glucose Monitoring System Max
Rightest Blood Glucose Monitoring System Max Plus
GE Blood Glucose Monitoring System Max
GE Blood Glucose Monitoring System Max Plus

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

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indication(s) for use below:

2. Indication(s) for use:

   Rightest Blood Glucose Monitoring System Max
   Rightest Blood Glucose Monitoring System Max 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. It is intended to be used by a single person and should not be shared.

   Rightest Blood Glucose Monitoring System Max 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. It 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 Monitoring System Max is comprised of the Rightest Blood Glucose Test Strip Max and the Rightest Meter Max.

   Rightest Blood Glucose Monitoring System Max Plus
   Rightest Blood Glucose Monitoring System Max Plus with Bluetooth function 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. It is intended to be used by a single person and should not be shared.

   Rightest Blood Glucose Monitoring System Max Plus with Bluetooth function 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. It 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 Monitoring System Max Plus is comprised of the Rightest Blood Glucose Test Strip Max and the Rightest Meter Max Plus.

GE Blood Glucose Monitoring System Max
GE Blood Glucose Monitoring System Max 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. It is intended to be used by a single person and should not be shared.

GE Blood Glucose Monitoring System Max 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. It 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 Monitoring System Max is comprised of the GE Blood Glucose Test Strip Max and the GE Meter Max.

GE Blood Glucose Monitoring System Max Plus
GE Blood Glucose Monitoring System Max Plus with Bluetooth function 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. It is intended to be used by a single person and should not be shared.

GE Blood Glucose Monitoring System Max Plus with Bluetooth function 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. It 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 Monitoring System Max Plus is comprised of the GE Blood Glucose Test Strip Max and the GE
Meter Max Plus.

3. Special conditions for use statement(s):

- Intended for self-testing.
- For use with capillary whole blood only.
- For over-the-counter use and single-patient use only.
- Not for use on critically ill patients.
- Not for use on neonates.
- Not for screening or diagnosis of diabetes.
- 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.

- The blood glucose result of the meter may be much lower than "true glucose levels" in the hyperglycemic-hyperosmolar state, with or without ketosis.
- Low blood sugar (hypoglycemia), in some cases, diabetes can trigger low blood pressure.
- Test results may be falsely low if the patient is severely hypotensive, severely dehydrated, in shock, or in a hyperosmolar state (with or without ketosis).
- Not for use at altitudes greater than 10,000 feet (3,048 meters).
- Not for use for hematocrit < 10% or > 70%. Check with your healthcare provider if you do not know your hematocrit level.
- Alternative site testing (palm, forearm) results should not be used to calibrate Continuous Glucose Monitoring (CGM) devices.
- AST should not be used to test for insulin dose calculations.
- AST should not be used when glucose is changing rapidly (e.g., after drinking, after meal, after exercise).

4. Special instrument requirements:

   Rightest Meter Max
   Rightest Meter Max Plus
   GE Meter Max
   GE Meter Max Plus

I. Device Description:

Rightest Blood Glucose Monitoring System Max and Rightest Blood Glucose Monitoring System Max Plus, consist of the following devices

Blood Glucose Meter, Blood Glucose Test Strip, Control Solution, lancing device and sterile lancets. The Blood Glucose Meter, Blood Glucose Test Strips, and Lancing Device are manufactured by BIONIME Corporation. The Rightest Blood Glucose Monitoring System Max Plus has Bluetooth functionality while the Rightest Blood Glucose Monitoring System Max does not.

Rightest Meter Max and Rightest Meter Max Plus, when used with the Rightest Test Strips Max, quantitatively measure glucose in fresh whole blood samples from capillary. The performance of Rightest Blood Glucose Monitoring System Max and Rightest Blood Glucose Monitoring System Max Plus are verified by the Rightest Control Solution GC700.

GE Blood Glucose Monitoring System Max and GE Blood Glucose Monitoring System Max Plus, consist of the following devices:

Blood Glucose Meter, Blood Glucose Test Strip, Control Solution, lancing device and sterile lancets. The Blood Glucose Meter, Blood Glucose Test Strips, and Lancing Device are manufactured by BIONIME Corporation. The GE Blood Glucose Monitoring System Max Plus has Bluetooth functionality while the GE Blood Glucose Monitoring System Max does not.

GE Meter Max and GE Meter Max Plus, when used with the GE Test Strips Max, quantitatively measure glucose in fresh whole blood samples from capillary. The performance of GE Blood glucose monitoring System Max and GE Blood glucose monitoring System Max Plus are verified by the Rightest Control Solution GC700.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Rightest BGMS GM720

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

   k140210

3. Comparison with predicate: The Rightest BGMS Max and GE BGMS Max are identical in all aspects and only differ in name. The Rightest BGMS Max Plus and GE BGMS Max Plus are identical in all aspects and only differ in name.

Similarities			
Item	**Rightest BGMS Max and GE BGMS Max**	**Rightest BGMS Max Plus and GE BGMS Max Plus**	**Rightest BGMS (Predicate device)**
Indications for Use	Intended for the quantitative measurement of glucose in fresh capillary blood samples by people with diabetes at home to monitor the effectiveness of diabetes control.		Same
Measurement Technology	Dehydrogenase electrochemical sensor		Same
Sample Type	Fresh capillary whole blood		Same
Minimum Sample Volume	0.75 microliter		Same
Test Time	5 seconds		Same

Differences			
Item	**Rightest BGMS Max and GE BGMS Max**	**Rightest BGMS Max Plus and GE BGMS Max Plus**	**Rightest BGMS**
Measurement Range	10-600 mg/dL	10-600 mg/dL	20-600 mg/dL
Wireless Module	None	Bluetooth 4.0	None

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

ISO 14971 Medical devices - Application of risk management to medical devices.

IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirement for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

CLSI EP07-A2 – Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition.

L. Test Principle:

The subject devices utilize electrical characteristic technology for measuring glucose levels in human blood. A relatively small drop of blood (minimum volume of 0.75 µL) is placed on the disposable test strip coated with glucose oxidase which interacts with the meter. Within 5 seconds after testing, the blood glucose level is indicated on the meter's digital display screen.

M. Performance Characteristics (if/when applicable):

The only differences between the four devices in this submission are the names and the presence and absence of Bluetooth functionality. Therefore, the performance studies below were conducted using the Rightest/GE Meter Max Plus as a representative meter.

1. Analytical performance:

a. Precision/Reproducibility:

Within-run (Repeatability)

The sponsor performed repeatability precision studies using venous whole blood samples adjusted to five glucose levels (30-50, 51-110, 111-150, 151-250, 251-400 mg/dL). Each glucose concentration levels was analyzed in replicates of 10 with three test strip lots and on 30 meters (10 meters per test strip lot) for a total of 300 tests per each glucose level. Results are summarized below:

Glucose Level (mg/dL)	n	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
30-50	300	1	44.3	1.8	4.0
		2	46.1	1.9	4.0
		3	45.4	1.7	3.8
51-110	300	1	95.1	1.9	2.0
		2	93.8	2.1	2.2
		3	94.1	2.0	2.1

Glucose Level (mg/dL)	n	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
111-150	300	1	135.6	3.2	2.4
		2	131.9	3.1	2.4
		3	132.7	3.3	2.5
151-250	300	1	200.2	2.9	1.5
		2	195.2	3.0	1.5
		3	197.6	3.0	1.5
251-400	300	1	300.8	5.0	1.7
		2	292.3	5.2	1.8
		3	295.6	4.6	1.6

Intermediate Precision

Intermediate precision was assessed using five levels of control solutions (30-50, 51-110, 111-150, 151-250, 251-400 mg/dL) over 10 days. Ten replicates were tested per meter, test strip lot and glucose concentration for a total of 10 replicates collected per glucose level for a total of 300 results for each glucose level. Results are summarized below:

Glucose Level (mg/dL)	n	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
30-50	300	1	54.6	1.4	2.6
		2	56.6	1.7	2.9
		3	55.5	1.5	2.7
51-110	300	1	119.4	2.8	2.3
		2	116.1	2.7	2.3
		3	116.8	2.5	2.2
111-150	300	1	149.2	2.6	1.8
		2	155.2	2.9	1.9
		3	149.8	2.5	1.7
151-250	300	1	217.4	4.0	1.8
		2	217.6	4.1	1.9
		3	219.8	3.8	1.7
251-400	300	1	271.6	4.4	1.6
		2	262.9	4.3	1.6
		3	266.6	4.4	1.7

b. Linearity/assay reportable range:

Linearity assessment was performed using venous whole blood samples adjusted to 14 glucose concentrations ranging from 12.2 to 614 mg/dL (12.2, 27.4, 52.2, 108, 132.5, 196.5, 271 , 322, 345.5, 420.5, 455.5, 511.5, 572.5, and 614 mg/dL) and three test strip lots and three meters. The results were compared to values obtained from

duplicate sample measurements using the comparator method (YSI 2300 Analyzer). The following are the results from the regression analysis:

Lot	Slope	y-intercept	R^2
1	0.9838	1.4412	0.9996
2	0.9827	1.052	0.9995
3	0.9832	1.5748	0.9996
3 Lots Combined	0.9833	1.3229	0.9996

The results of the study support the sponsor's claimed glucose measuring range of 10 to 600 mg/dL for this device. The meter displays "LO" with glucose values below 10 mg/dL and "HI" with glucose values over 600 mg/dL. The LO and HI functions were validated and were demonstrated to function as intended.

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

Traceability

The system is traceable to the certified glucose reference material NIST SRM 917b.

Test Strip Stability

Stability protocols and acceptance criteria for the Rightest/GE Test Strips Max were reviewed and found to be acceptable to support closed-vial stability of 26 months and open-vial stability of 4 months when test strips are stored at 39 to 86 °F (4 to 30°C), 10-90% relative humidity. The labeling instructs the users not to freeze the test strips.

d. *Detection limit:*

The reportable range is 10-600 mg/dL. This range was verified by the linearity study (M.1.b above).

e. *Analytical specificity:*

Interference studies were performed by spiking 31 exogenous substances, endogenous substances into venous whole blood with three glucose levels (50-70, 110-130, and 225-270 mg/dL) as measured on the YSI 2300 Analyzer. Interfering substances were tested at each glucose level in replicates of 10 using three test strip lots and three meters. The difference between the test sample (with interferent) as measured on the meter and the control sample (without interferent) as measured on the meter were calculated. The sponsor defined no significant interference as ≤ 10% between test and control mean. The highest tested concentration of each substance tested with no significant interference are summarized in the following table:

Potential Interfering Substance	Highest concentration with no significant interference (mg/dL)
Acetaminophen	20
Ascorbic acid	3
Dopamine HCl	2
EDTA	200
Gentisic acid	3.5
Heparin	500 U/ml
Ibuprofen	50
L-Dopa	2
Methyldopa	2.5
Salicylic acid	60
Tolazamide	40
Tolbutamide	100
Bilirubin-conjugated	50
Bilirubin-unconjugated	50
Cholesterol	500
Creatine HCl	10
Glutathione reduced	30
Hemoglobin	21,500
Sodium chloride	1052
Triglycerides	1500
Uric acid	12.35
Maltose	1,800
Xylose	8
Galactose	200
Icodextrin	1100
Mannitol	0.09
Sorbitol	0.09
Xylitol	0.09
Lactilol	0.09
Isomalt	0.09
Maltitol	0.09

The sponsor has the following statements in their labeling:

- If you have a condition that may cause your blood levels of uric acid to increase more than 12 mg/dL, such as kidney disease or gout, then the results from your meter may not be correct.
- The meter result may not be correct when Xylose blood concentration > 8 mg/dL, this meter should not be use during or following xylose absorption therapy.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

   a. *Method comparison with predicate device:*

      See section 3(c) below.

   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 device accuracy in the hands of the intended users, the sponsor conducted a user evaluation study involving 357 lay user participants who collected and tested samples from their own fingertip, palm, and forearm. Results were analyzed by comparing blood glucose results obtained by the lay users with the Rightest/GE Blood Glucose Monitoring System Max/Max Plus against results obtained using a laboratory comparator method (YSI 2300 analyzer). Glucose concentrations in the samples ranged from approximately 51.3 to 471 mg/dL as measured by the laboratory reference method. Results are summarized in the tables below:

Source	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Fingertip	230/351 (65.5%)	338/351 (96.3%)	350/351 (99.7%)	351/351 (100%)
Palm	185/351 (52.7%)	309/351 (88.0%)	350/351 (99.7%)	351/351 (100%)
Forearm	166/350 (47.4%)	302/350 (86.3%)	348/350 (99.4%)	350/350 (100%)

      Results of regression analysis:
      Finger: $y = 1.00x + 0.35$
      Palm: $y = 1.02x + 1.27$
      Forearm: $y = 0.98x + 3.04$

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

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   The sponsor provided the following information for expected glucose values for persons without diabetes:

   Normal plasma glucose range for people without diabetes:
   - Fasting and before meal: < 100 mg/dL (5.6 mmol/L)
   - 2 hours after meals: < 140 mg/dL (7.8 mmol/L)

   Reference:
   American Diabetes Association. Standards of Medical Care In Diabetes. Diabetes Care – 2018 Jan; 41 (Supplement 1): S1-S2

N. Instrument Name:

Rightest Blood Glucose Monitoring System (BGMS) Max
Rightest BGMS Max Plus
GE BGMS Max
GE BGMS Max Plus

O. System Descriptions:

1. Modes of Operation:
   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?

   Rightest BGMS Max and GE BGMS Max: Yes _____ or No ____X____
   Rightest BGMS Max Plus and GE BGMS Max Plus: 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.

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:
   Calibration is automatic and is performed at the time of quality control testing. There is no user input for coding.

6. Quality Control:
   Three levels of glucose control solutions (Level 1, Level 2, and Level 4) are available with this system, but are sold separately. Recommendations on when to test the control materials are provided in the labeling. The user is instructed to repeat testing with a new strip, or run a quality control test, or contact their healthcare profession if test results are unusually high or low. If quality control test results are out of range, the user is advised to repeat the test. If problems continue, the user is cautioned not to use the meter and to contact the distributor.

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

1. Hematocrit Study:
   To evaluate the effect of hematocrit on the Rightest/GE Blood Glucose Monitoring System Max/Max Plus, venous blood samples were adjusted to hematocrit levels of 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65% and 70%. Each hematocrit level was tested at five glucose concentration intervals (30-50 mg/dL, 50-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, and 251-400 mg/dL). Results from the meter were compared to results obtained using a laboratory-based comparator measurement (YSI 2300 analyzer). The results support the labeled hematocrit claim of 10-70%.

2. Altitude Testing:
   To evaluate the effect of altitude on the Rightest/GE Blood Glucose Monitoring System Max/Max Plus, meters were tested at 0 ft (m), 3280 ft (1000 m), 6561 ft (2000 m), and 10,745 ft (3275 m) above sea level. Venous blood samples from 5 healthy volunteers were each prepared at three glucose concentration levels (50-75 mg/dL, 80-120 mg dL, and 270-330 mg/dL) and tested at each altitude. Results were compared to results obtained using a laboratory-based comparator measurement (YSI 2300 analyzer) and demonstrated that altitudes from 0 up to 10,745 ft (3275 m) above sea level have no significant effect on blood glucose measurements.

3. System Operating Conditions Testing:
   Temperature and humidity operating conditions were evaluated using venous blood samples at 2 glucose concentration ranges, (60-100 mg/dL and150-300 mg/dL) to evaluate temperatures ranging from 6ºC (42.8 ºF) to (111.2 ºF) and relative humidity from 10% to 90%. Six 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 sponsor's claimed operating conditions in the labeling that the system can be used in conditions of 43-111°F (6-44°C) and relative humidity from 10-90%.

4. Infection Control and Robustness Studies:
   The Rightest/GE Blood Glucose Monitoring System Max/Max Plus are intended for single-patient use. Disinfection efficacy testing on the surface materials of the meter demonstrated complete inactivation of duck hepatitis B virus (HBV) with the chosen disinfectant, CaviWipes Disinfecting Towelettes (EPA Registration Number 46781-8). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or in the external materials of the meter after 520 cleaning and disinfection cycles designed to simulate 5 years of single-patient use for the Rightest/GE Blood Glucose Monitoring System Max/Max Plus. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

5. Sample Volume Study:
   To verify the minimum sample volume claim, venous whole blood samples with nine volumes (0.60, 0.65, 0.70, 0.75, 0.80, 1.00, 1.25, 2.00, and 3.00 µL) were tested. Sample concentrations included three glucose levels (50-75 mg/dL, 80-120 mg/dL, and 270-330 mg/dL) and were tested at each volume. Values obtained with the candidate device were compared to values obtained using a laboratory-based comparator method (YSI 2300 analyzer). Results support the claimed minimum sample volume of 0.75 µL. The meter displays and error message when insufficient sample volume is applied to the test strip. The sponsor provided validation studies demonstrating that this error feature functions as intended.

6. Used Strip Error Functionality Test:
   A study was performed demonstrating that the Rightest/GE Blood Glucose Monitoring System Max/Max Plus displays an error rather than a measurement result when a used strip is inserted for testing.

7. Electromagnetic compatibility (EMC) and Electrical Safety:
   The sponsor provided appropriate documentation certifying that electromagnetic (EMC) testing was performed and the systems were found to be compliant.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

R. Conclusion:

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