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

A. 510(k) Number:

K170143

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whold 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:

Rightest Blood Glucose Monitoring System GM280
Rightest Blood Glucose Monitoring System GM280B
GE Blood Glucose Monitoring System 180
GE Blood Glucose Monitoring System 182

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 GM280

   The Rightest Blood Glucose Monitoring System GM280 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 GM280 is intended to be used by a single person and should not be shared.

   The Rightest Blood Glucose Monitoring System GM280 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 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 GS280 is used with Rightest meter GM280 for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

   Rightest Blood glucose monitoring System GM280B

   The Rightest Blood Glucose Monitoring System GM280B 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 GM280B is intended to be used by a single person and should not be shared.

   The Rightest Blood Glucose Monitoring System GM280B 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 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 GS280 is used with Rightest meter GM280B for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

GE Blood glucose monitoring System 180

The GE Blood Glucose Monitoring System 180 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 180 is intended to be used by a single person and should not be shared.

The GE Blood Glucose Monitoring System 180 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 180 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 Strip 180 is used with GE Blood Glucose Monitoring Meter 180 for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

GE Blood glucose monitoring System 182

The GE Blood Glucose Monitoring System 182 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 182 is intended to be used by a single person and should not be shared.

The GE Blood Glucose Monitoring System 182 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 182 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 Strip 180 is used with GE Blood Glucose Monitoring Meter 182 for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

3. Special conditions for use statement(s):

- These systems can only use with capillary whole blood samples.
- Not for screening or diagnosis of diabetes mellitus.
- Not for use in the critically ill.
- These systems should not be used for neonates.
- These devices are 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 Contains Nonbinding Recommendations 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.
- Severe dehydration and excessive water loss may cause inaccurately low results.
- Patients going through oxygen therapy may yield falsely low results
- Storage of strips near bleach as well as bleach containing products will affect the results of the Rightest® Test Strips.
- Do not use at altitudes greater than 10,000 feet (3,048 meters).
- Hematocrit range is 20–60%. Check with your healthcare provider if you do not know your hematocrit level.
- If you are taking high dose of vitamin C (blood concentration > 3 mg/dL), the result from your meter may not be correct.
- If you have a condition that may cause your blood levels of uric acid to increase (uric acid >12 mg/dL), such as kidney disease or gout, then the results from your meter may not be correct.
- DO NOT test on the palm or forearm to calibrate continuous glucose monitors (CGMs).
- DO NOT test on the palm or forearm if you are testing for insulin dose calculations or hypoglycemia (Low blood glucose).
- Do not test the blood sample from palm or forearm when glucose is changing rapidly(senarios: after drinking, after meal, after exercise).

4. Special instrument requirements:

   Rightest Blood Glucose Meter GM280
   Rightest Blood Glucose Meter GM280B
   GE Blood Glucose Meter 180
   GE Blood Glucose Meter 182

I. Device Description:

Rightest GM280 Blood Glucose Monitoring System, Rightest 280B Blood Glucose Monitoring System, GE 180 Blood Glucose Monitoring System, and GE 182 Blood Glucose Monitoring System consists of the following devices: Blood Glucose Meter, Blood Glucose Test Strip, three levels of Control Solutions (Level 1, Level 2 and Level 4), lancing device and sterile lancets. GM280B and GE182 Blood Glucose Monitoring Systems also containing Bluetooth connectivity capabilities.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bionime Corporation GE333 Blood Glucose Monitoring System

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

   K143387

3. Comparison with predicate:

   The different models of the proposed devices are identical except in name, two model (Rightest 280B and GE182) have Bluetooth capabilities.

Similarities			
Item	Device		Predicate
	Rightest Blood Glucose Monitoring System GM280	Rightest Blood Glucose Monitoring System GM280B	GE333 Blood Glucose Monitoring System k143387
	GE Blood Glucose Monitoring System 180	GE Blood Glucose Monitoring System 182	
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	Glucose Oxidase Electrochemical Sensor		Same
Sample Type	Capillary whole blood		Same
Minimum Sample Volume	0.75 μL		Same
Primary Site Testing	Fingertip		Same
Alternative Site Testing	Forearm, Palm		Same
Unit of Measurement	mg/dL		Same
Measuring Range	20-600 mg/dL		Same
Measuring Time	5 seconds		Same
Hematocrit	20-60 %		Same
Control Solution	3 levels (Level 1, 2, and 4) Rightest Control Solution GC550		Same
Maximum Altitude	3275 m (10745 feet)		Same
Operating Conditions	Temperature 10 ~ 40℃ (50 ~104 ℉), 10 ~ 90% Relative Humidity		Same
Meter Storage Conditions	-10 ~ 60℃ (14 ~140 ℉)		Same
Test Strip Storage Conditions	4 ~ 30℃ (39 ~86 ℉), 10-90		Same

Similarities			
Item	Device		Predicate
	Rightest Blood Glucose Monitoring System GM280	Rightest Blood Glucose Monitoring System GM280B	GE333 Blood Glucose Monitoring System k143387
	GE Blood Glucose Monitoring System 180	GE Blood Glucose Monitoring System 182	
	% relative humidity		
Test Strip Shelf Life (After Opening)	3 months		Same
Memory Capacity	500 blood glucose test results with date and time		Same
Power Saving	Turn off automatically 2 minutes after last user action / Press the main button for 3 seconds.		Same
Coding	Auto coding		Same
Monitor	LCD display		Same
Backlight	No		Same

Differences			
Item	Device		Predicate
	Rightest GM280	Rightest GM280B	GE333 Blood Glucose Monitoring System k143387
	GE180	GE182	
Wireless module	None	Bluetooth 4.0 (Low energy)	Bluetooth 4.0 (Low energy)
Power Supply	One CR2032 battery		Two AAA batteries
Battery Life	1000 tests		About 800 tests
LCD display area	34 mm*27.5mm		39mm*39.5mm
Meter Weight	43.0± 5g with batteries		81.0 ± 5g with batteries
Color	white/gray		white/green

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 Rightest GM280 Blood Glucose Monitoring System, Rightest 280B Blood Glucose Monitoring System, GE 180 Blood Glucose Monitoring System, and GE 182 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):

There are no differences between the Rightest GM280 Blood Glucose Monitoring System, Rightest 280B Blood Glucose Monitoring System, GE 180 Blood Glucose Monitoring System, and GE 182 Blood Glucose Monitoring System except for Bluetooth capabilities in the GM280B and GE182 meters. Therefore, analytical studies were conducted on the GM280B device to support the four systems.

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. Results are summarized below:

Glucose Level (mg/dL)	Lot	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	1	42.1	1.5	3.5%
	2	41.2	1.2	2.9%
	3	40.4	1.3	3.2%
51-110	1	98.8	1.9	1.9%
	2	96.4	2.4	2.5%
	3	95.7	2.4	2.5%
111-150	1	134.3	3.1	2.3%
	2	129.3	3.2	2.4%
	3	129.5	2.7	2.1%
151-250	1	233.7	5.0	2.1%
	2	227.6	5.1	2.3%
	3	227.7	4.5	2.0%
251-400	1	383.1	6.7	1.8%
	2	375.6	6.9	1.8%
	3	373.8	5.6	1.5%

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	38.9	1.0	2.7%
	2	38.2	1.2	3.1%
	3	37.4	1.2	3.2%
51-110	1	96.4	1.6	1.6%
	2	96.6	1.5	1.5%
	3	95.9	1.6	1.6%
251-400	1	280.6	4.4	1.6%
	2	276.3	3.6	1.3%
	3	278.6	4.2	1.5%

b. *Linearity/assay reportable range:*

Linearity was assessed with three lots of GS280 Blood Glucose Test Strips. Each test strip lot was tested with three GM280 Blood Glucose Monitoring Systems using blood samples spiked to 15 glucose levels (0, 13.7, 24.0, 57.6, 117, 165, 225, 265, 325, 375, 429, 475, 535, 552, and 635 mg/dL). Each sample was measured in triplicate with each Rightest Blood Glucose Monitoring System GM280 and measured in duplicate with a laboratory method (YSI 2300 glucose analyzer). The observed meter values were averaged and compared with the mean of duplicate reference method measurements

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

Lot 1: $y = 0.9929x + 1.5820$; $R^2 = 0.9992$

Lot 2: $y = 0.9926x + 1.1366$; $R^2 = 0.9983$

Lot 3: $y = 0.9917x + 2.3442$; $R^2 = 0.9992$

These studies support the claimed analytical measuring range of the systems. If a sample reading falls outside of the measuring range of the device, a "LO" or "HIGH" message appears instead of a value. These features were tested and shown to function as intended.

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

Traceability

The systems are 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 to support the claimed 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:

The interference study for Rightest GM280 BGMS was performed using 2 glucose concentration levels (50-100 and 250-350 mg/dL) of venous blood samples and 26 interference substances. 10 meters and 3 lots of test strips were used to perform 10 replicates per lot and compared to an established laboratory reference method (YSI 2300 Analyzer). The sponsor defined significant interference as of bias greater than ±10% (vs reference method). The compounds at the concentrations listed below did not demonstrate significant interference:

Potential Interferent	**Highest concentration tested at which no significant interference is observed (mg/dL)**
Acetaminophen	20
Ascorbic Acid	3
Dopamine HCl	1.25
EDTA	0.1
Gentisic Acid	1.8
Heparin	18.75 U/ml
Ibuprofen	50
L-Dopa	3
MethylDopa	1.5
Pralidoxime iodide	4
Salicylic Acid	60
Tetracycline	1.5
Tolazamide	40
Tolbutaminde	64
Bilirubin-unconjugated	50
Cholesterol	700
Creatinine HCl	10
Glutathione reduced	40
Hemoglobin	6000
Triglycerides	3000
Uric Acid	12
Maltose	280
Xylose	200
Galactose	200
Lactose	50
Icodextrin	1000

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

- If you are taking high dose of vitamin C (blood concentration > 3 mg/dL), the result from your meter may not be correct.
- If you have a condition that may cause your blood levels of uric acid to increase (uric acid ≥12 mg/dL), such as kidney disease or gout, then the results from your meter may not be correct.

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 the accuracy of the Rightest Blood Glucose Monitoring System GM280/GM280B in the hands of the intended users, 135 lay users tested their own fingertip capillary blood samples. 135 users also took capillary blood samples from their palms and 133 users took capillary samples from their forearms. Results were compared to the measurements made using a laboratory comparator method (YSI 2300 analyzer). Samples ranged in glucose concentration from 66 – 350 mg/dL. The

meter results relative to YSI are summarized below:

Testing Site	Linear Equation	R^2
Fingertip	y = 0.99x + 1.33	0.99
Palm	y = 0.99x + 1.81	0.99
Forearm	y = 0.96x + 4.40	0.99

Fingertip Capillary Samples

For glucose concentrations <75 mg/dL

Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL
2/4 (50%)	4/4 (100%)	4/4 (100.0%)

For glucose concentrations ≥75mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
87/131 (66.4%)	119/131 (90.8%)	129/131 (98.5%)	131/131 (100%)

Palm Capillary Samples (AST Samples)

For glucose concentrations <75 mg/dL

Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL
2/4 (50%)	4/4 (100%)	4/4 (100.0%)

For glucose concentrations ≥75mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
75/131 (57.3%)	114/131 (87.0%)	128/131 (97.7%)	129/131 (98.5%)

Forearm Capillary Samples (AST Samples)

For glucose concentrations <75 mg/dL

Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL
1/3 (33%)	2/3 (66.7%)	3/3 (100%)

For glucose concentrations ≥75mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
67/130 (51.5%0	105/130 (80.8%)	125/130 (96.2%)	129/130 (99.2%)

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

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

American diabetes association. Standards of medical care in diabetes-2016. 2016;39 (supp. 1 diabetes Care): S8-S16

N. Instrument Name:

Rightest Blood Glucose Monitoring Meter GM280
Rightest Blood Glucose Monitoring Meter GM280B
GE Blood Glucose Monitoring Meter 180
GE Blood Glucose Monitoring Meter 182

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 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 Rightest GM280 Blood Glucose Monitoring System, Rightest 280B Blood Glucose Monitoring System, GE 180 Blood Glucose Monitoring System, GE 182 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 minimum sample volume of 0.75for 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 on system performance, 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, 3280, 6561, and 10745 feet above 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 effect of different hematocrit levels was evaluated using whole blood. Rightest Blood Glucose Monitoring System GM280/GM280B 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 laboratory comparotor method (YSI).. Results of samples at each hematocrit level were compared to samples measured with an established laboratory reference method (YSI) and support the claimed hematocrit range of 20-60%.

4. Test System Operating Conditions

Three Rightest Blood Glucose Monitoring System GM280/GM280B 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 °F/ 10% RH, 50 °C/ 90% RH, 77 °C/ 10% RH, 77 °C/ 90% RH, 104 °C/ 10% RH, 104 °C/ 90% RH. The results of this study supported the sponsor's claimed operating conditions of 50 °F-104 °F and a relative humidity range of 10% to 90%.

5. EMC Testing

The sponsor provided documentation certifying that acceptable electromagnetic testing (EMC) had been performed and the device system was found compliant.

6. Infection Control Studies

The device is intended for a single-patient use only. Disinfection efficacy studies were performed on the materials comprising the polycarbonate, acrylonitrile butadiene styrene plus polycarbonate meters by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Cavi Wipes disinfecting towelettes (EPA Registration Number 46781-8). 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 cleaning and disinfection procedures 8 times a month for a total of 550 times in a meter's five-year lifetime. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7. 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 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.