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

I Background Information:

A 510(k) Number

K231192

B Applicant

Bionime Corporation

C Proprietary and Established Names

RIGHTEST Blood Glucose Monitoring System Max Tel

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 device

B Measurand:

Glucose in capillary whole blood from the fingertips, forearm, or palm

C Type of Test:

Quantitative amperometric assay (glucose dehydrogenase-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 Max Tel 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 Tel 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 Tel is comprised of the RIGHTEST Meter Max Tel and the RIGHTEST Blood Glucose Test Strip Max.

C Special Conditions for Use Statement(s):

- OTC - Over The Counter
- For in vitro diagnostic use only
- For single-patient use only
- For self-testing
- Not for use on neonates
- RIGHTEST Blood Glucose Monitoring System Max Tel can only use with capillary whole blood samples.
- DO NOT use the results from alternative sites (palm, forearm) for insulin dose calculations.
- DO NOT use the results from alternative site testing (palm, forearm) to calibrate Continuous Glucose Monitoring (CGM) devices.
- Not for use on critically ill patients, severely hypotensive individuals, patients in shock, dehydrated patients, or in a hyperglycemic-hyperosmolar state with or without ketosis.
- Do not use at altitudes greater than 10,000 feet (3,048 meters).
- Severe dehydration and excessive water loss may cause inaccurately low results.
- Not for screening or diagnosis of diabetes mellitus.
- 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 Max Tel

IV Device/System Characteristics:

A Device Description:

RIGHTEST Blood Glucose Monitoring System Max Tel is designed to quantitatively measure the glucose concentration in fresh capillary whole blood from fingertip, palm or forearm.

RIGHTEST Blood Glucose Monitoring System Max Tel consists of RIGHTEST Blood Glucose Meter Max Tel, Blood Glucose Test Strip Max, RIGHTEST Control Solution GC700 (Level 1, Level 2 and Level 4), RIGHTEST Lancing Device and Sterile Lancets (K221062). The RIGHTEST Blood Glucose Test Strip Max is the same as Test Strip Max cleared in K173638. The test strips, control solutions and Lancing Device can be purchased separately.

B Principle of Operation:

The RIGHTEST Blood Glucose Monitoring System Max Tel is designed to quantitatively measure the glucose concentration in fresh capillary whole blood. The glucose measurement is achieved by using the amperometric detection method that uses glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) based chemistry. When a drop of blood is applied to the test strip it is pulled into the test strip through capillary action. Glucose in the sample reacts with test strip chemistry generating electrons and producing a current that is proportional to the glucose concentration in the sample. After the reaction time, the detected current is calculated by the meter and the resulting glucose concentration is displayed by the meter. The RIGHTEST Blood Glucose Monitoring System Max Tel system reports glucose results as plasma glucose.

C Instrument Description Information:

1. Instrument Name:

   RIGHTEST Blood Glucose Meter Max Tel

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:

   Fresh capillary whole blood from user's fingertips, palm, or forearm. Samples are to be tested immediately upon collection. The whole blood sample is applied directly to the test strip by capillary action.

4. Calibration:

   No user calibration is required. The meter is automatically coded.

5. Quality Control:

   Three levels of control solution (Level 1, Level 2, Level 4) are for use to perform quality control testing to check whether the system is working properly. Instructions on when to perform a control test, details about the control solution, performing a control test, understanding out-of-range control results are provided in the labeling. User needs to enter the control solution mode (CS mode) on the meter to perform a quality control test. Control solution ranges are printed on the test strip vial label.

V Substantial Equivalence Information:

A Predicate Device Name(s):

RIGHTEST Blood Glucose Monitoring System Max Plus

B Predicate 510(k) Number(s):

K173638

C Comparison with Predicate(s):

Device & Predicate Device(s):	K231192	K173638
Device Trade Name	RIGHTEST Blood Glucose Monitoring System Max Tel	RIGHTEST Blood Glucose Monitoring System Max Plus
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. 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.	Same
Measurement Technology	Glucose dehydrogenase-FAD	Same
Sample Type	Fresh capillary whole blood	Same
Minimum Sample Volume	0.75 microliter	Same
Operating Conditions	43 to 111 ℉ (6 to 44 ℃), 10 - 90% RH	Same
General Device Characteristic Differences		
Measuring Range	50 - 550 mg/dL	10 - 600 mg/dL
Data Transmission	N/A	Bluetooth
Meter Power Source	Non-replaceable and Rechargeable Lithium battery (3.7 V)	Two CR2032 batteries

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. September 29, 2020.

CLSI EP07 3rd Edition: Interference Testing in Clinical Chemistry.

ISO14971-Third edition 2019-12: Medical Devices-Application of Risk Management to Medical Devices.

AAMI TIR57: 2016: Principles for medical device security - Risk management.

IEC 61326-1 Edition 3.0 2020-10: Electrical equipment for measurement control and laboratory use - EMC requirements - Part 1: General requirements.

IEC- 62304 Edition 1.1 2015-06: Medical device software-Software life cycle processes.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Within-run precision

Within-run precision (repeatability) studies were performed with human venous blood samples at 5 glucose concentration ranges (30-50, 51-110, 111-150, 151-250, 251-400 mg/dL). Each sample was tested ten times on each of 10 meters using three lots of test strips for a total of 300 tests per glucose concentration. Results are summarized below:

Glucose Level (mg/dL)	Strip Lot	N	Mean (mg/dL)	SD (mg/dL)	%CV
30 to 50	1	100	41.8	1.5	3.6
	2	100	42.9	1.1	2.7
	3	100	41.0	1.1	2.8
	Combined	300	41.9	1.3	3.1
51 to 110	1	100	91.5	2.0	2.2
	2	100	92.0	2.2	2.4
	3	100	90.6	2.2	2.4
	Combined	300	91.3	2.1	2.3
111 to 150	1	100	128.4	2.5	2
	2	100	129.8	3	2.3
	3	100	129.1	2.3	1.7
	Combined	300	129.1	2.6	2.0
151 to 250	1	100	226.3	4.4	1.9
	2	100	224.9	4.5	2.0

Glucose Level (mg/dL)	Strip Lot	N	Mean (mg/dL)	SD (mg/dL)	%CV
	3	100	225.3	4.4	1.9
	Combined	300	225.5	4.4	2.0
251 to 400	1	100	338.6	6.7	2.0
	2	100	346.3	6.0	1.7
	3	100	334.1	5.7	1.7
	Combined	300	339.7	6.1	1.8

Intermediate Precision

Intermediate (day to day) precision was evaluated for 10 days using 5 levels of control solutions, 3 test strip lots, and 10 meters. Each sample level was measured once a day with each meter and each test strip lot for 10 days, for a total of 300 replicates per level. Results are summarized below:

Glucose Level (mg/dL)	Strip Lot	N	Mean (mg/dL)	SD (mg/dL)	%CV
30 to 50	1	100	38.2	1.2	3.0
	2	100	38.0	1.3	3.5
	3	100	35.4	1.1	3.1
	Combined	300	37.2	1.2	3.2
51 to 110	1	100	105.4	2.3	2.2
	2	100	105.2	2.2	2.1
	3	100	101.1	2.0	2.0
	Combined	300	103.9	2.2	2.1
111 to 150	1	100	138.2	2.5	1.8
	2	100	136.8	2.6	1.9
	3	100	134.2	2.5	1.8
	Combined	300	136.4	2.5	1.8
151 to 250	1	100	207.5	2.3	1.1
	2	100	206.7	2.0	0.9
	3	100	201.7	2.4	1.2
	Combined	300	205.3	2.2	1.1
251 to 400	1	100	265.2	3.5	1.3
	2	100	264.7	4.5	1.7
	3	100	260.7	4.2	1.6
	Combined	300	263.5	4.1	1.6

2. Linearity:

Linearity of the RIGHTEST Blood Glucose Monitoring System Max Tel was evaluated using venous whole blood samples adjusted to 14 glucose levels ranging from 15 to ~ 616 mg/dL (15, 25, 57, 102, 142, 207, 256, 316, 348, 408, 464, 512, 556 and 616 mg/dL as measured by

comparator method YSI 2300 Analyzer), 3 lots of test strips and 3 meters. Test procedures were performed in 3 replicates per lot per concentration level. Blood glucose concentration values obtained on the RIGHTEST Blood Glucose Monitoring System Max Tel were compared to those obtained using comparator method YSI 2300 analyzer. The results of linear regression analysis are summarized below:

Test Strip Lot #	Slope	y-intercept	R^2-value
Lot 1	1.0193	-0.145	0.9998
Lot 2	1.0202	0.1988	0.9998
Lot 3	1.0163	0.3926	0.9997
Combined	1.0186	0.1488	0.9998

The results of the study support the sponsor's claimed glucose measurement range from 50 - 550 mg/dL. The meter displays "LO" with glucose values below 50 mg/dL and "HI" with glucose values over 550 mg/dL. The LO and HI functions were validated and were demonstrated to function as intended.

3. Analytical Specificity/Interference:

To assess potential interference, studies were performed by spiking 31 exogenous and endogenous substances into venous whole blood with three glucose levels (50-70, 110-130, and 225-270 mg/dL; as measured on the comparator YSI 2300 Analyzer). Each of these samples was divided into a test pool and a control pool, with the potential endogenous and exogenous interfering substances added to the test pool. Each sample was tested in replicates of 10. 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 highest tested concentrations of each substance tested with no significant interference (defined by the sponsor as ≤ 10% between test and control mean) are summarized in the following table:

Test Substance	Highest Concentration Tested with no Significant Interference
Acetaminophen	20 mg/dL
Ascorbic Acid	3 mg/dL
Dopamine HCl	0.09 mg/dL
EDTA	0.1 mg/dL
Gentisic Acid	1.8 mg/dL
Heparin	300 IU/dL
Ibuprofen	50 mg/dL
L-Dopa	0.75 mg/dL
Methyldopa	2 mg/dL
Salicylic Acid	60 mg/dL
Tolazamide	9 mg/dL

Test Substance	Highest Concentration Tested with no Significant Interference
Tolbutamide	72 mg/dL
Bilirubin-conjugated	30 mg/dL
Bilirubin-unconjugated	40 mg/dL
Cholesterol	500 mg/dL
Creatinine HCl	15 mg/dL
Glutathione reduced	4.6 mg/dL
Hemoglobin	1000 mg/dL
Sodium Chloride	1052 mg/dL
Triglycerides	1500 mg/dL
Uric acid	12 mg/dL
Maltose	480 mg/dL
Xylose	8 mg/dL
Galactose	60 mg/dL
Icodextrin	0.09 mg/dL
Mannitol	1800 mg/dL
Sorbitol	0.09 mg/dL
Xylitol	0.09 mg/dL
Lactitol	0.09 mg/dL
Isomalt	0.09 mg/dL
Maltitol	0.09 mg/dL

The sponsor has the following statements in their labeling:

- If you have a condition, such as kidney disease or gout, that may cause your blood levels of uric acid to rise to more than 12 mg/dL, the results from your meter may not be correct.
- If you are taking a high level of vitamin C (ascorbic acid level in your blood > 3 mg/dL), your blood glucose results may not be reliable. If you are unsure, ask your doctor.
- If you have a condition, such as jaundice, that may cause your blood levels of Conjugated Bilirubin to rise to more than 30 mg/dL, the results from your meter may not be correct.

4. Assay Reportable Range:

   Glucose 50 - 550 mg/dL.

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

   Traceability

The system is traceable to NIST (National Institute of Standards and Technology) standard reference material NIST SRM #917c. A method comparison was performed using the candidate device and a YSI 2300 comparator method.

Test Strip Stability
Test strip stability was assessed using real time stability and accelerated stability studies. Protocols and acceptance criteria were reviewed and found acceptable to support the labeling claims that the test strips are stable for 4 months after first being opened, and that closed vials are stable for 24 months when at the recommended storage temperatures 39ºF - 86ºF (4ºC - 30ºC) and 10 - 90% relative humidity. The labeling instructs the users not to freeze the test strips.

6. Detection Limit:

   The reportable range is 50 - 550 mg/dL. Please refer to the linearity in Section VII.A.2 above.

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:

   See lay-user performance study below in Section VII.C.3.

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):

Lay-User Performance Study

To assess the performance of the RIGHTEST Blood Glucose Monitoring System Max Tel in the hands of the intended users, the sponsor conducted a user evaluation study involving 370 lay user participants who collected and tested samples from their own fingertip, palm, and forearm using only the instructions from the product labeling in English. The data was collected using three test strip lots at four study sites. Results were analyzed by comparing blood glucose results obtained by the lay users with the Rightest Blood Glucose Monitoring System Max Tel against results obtained using a laboratory comparator method (YSI 2300 analyzer). Glucose concentrations in the samples ranged from approximately 52.5 to 537 mg/dL as measured by the comparator method, which includes 135 native samples below 80 mg/dL and 135 samples above 250 mg/dL. Results are summarized in the tables below:

System Accuracy Results for Entire Glucose range				
Sample Site	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Fingertip	231/370 (62.4%)	333/370 (90.0%)	365/370 (98.6%)	370/370 (100.0%)
Palm	211/370 (57.0%)	323/370 (87.3%)	360/370 (97.3%)	370/370 (100.0%)
Forearm	226/370 (61.1%)	316/370 (85.4%)	361/370 (97.6%)	370/370 (100.0%)

Regression Analysis	
Fingertip	$y = 0.997x – 1.91$; $R^2 = 0.995$
Palm	$y = 0.996x – 2.53$; $R^2 = 0.995$
Forearm	$y = 0.999x – 2.19$; $R^2 = 0.995$

Usability:
At the end of the lay user performance study, each participant was 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 with the RIGHTEST Blood Glucose Monitoring System Max Tel. From the sponsor's analysis of the questionnaire responses, the participants overall were satisfied with the ease of operation by following the instructions for use in the User's Manual and the overall performance of the RIGHTEST Blood Glucose Monitoring System Max Tel.

Readability:
A Flesch-Kincaid readability assessment was conducted on the user manual, Getting Started Guide and the test strip insert and demonstrated that the overall readability of the test strip insert, user manual and quick start guide was at an 8th grade level or lower.

D Clinical Cut-Off:

Not Applicable

E Expected Values/Reference Range:

The expected blood glucose values for people without diabetes:

< 100 mg/dL fasting
<140 mg/dL 2 hours after a meal

Reference: American Diabetes Association; Standards of Care in Diabetes—2023 Abridged for Primary Care Providers. Clin Diabetes 2 January 2023; 41 (1): 4–31.

F Other Supportive Instrument Performance Characteristics Data:

1. **Hematocrit Study**
   To evaluate the effect of hematocrit on the Rightest Blood Glucose Monitoring System Max Tel, venous blood samples were adjusted to 12 hematocrit levels of 10%, 15%, 20%, 25%, 30%, 35%, 42%, 50%, 55%, 60%, 65% and 70%. Each hematocrit level was tested at five glucose levels (~40 mg/dL, ~100 mg/dL, ~120 mg/dL, ~200 mg/dL, and ~340 mg/dL). Results from the meter were compared to results obtained using a laboratory-based comparator method (YSI 2300 analyzer). The results support the labeled hematocrit claim of 10-70%.

2. **Altitude Study**
   To evaluate the effect of altitude on the Rightest Blood Glucose Monitoring System Max Tel, 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 were prepared at three glucose concentration levels (~45 mg/dL, ~130 mg dL, and ~350 mg/dL) and tested at each altitude. Results were compared to results obtained using a laboratory-based comparator method (YSI 2300 analyzer) and demonstrated that altitudes up to 10,745 ft (3275 m) above sea level have no significant effect on blood glucose measurements.

3. **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 using three meters and three test strip lots. Sample concentrations included three glucose levels (61 mg/dL, 106 mg/dL, and 237 mg/dL) and were tested at each volume. Values obtained with the candidate device were compared to values obtained using the 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.

4. **System Operating Conditions Study**
   The effect of temperature and humidity operating conditions were evaluated using venous blood samples to evaluate temperatures ranging from 6°C (42.8°F) to 44°C (111.2°F) 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. Values were compared to results from the comparator method (YSI 2300 analyzer). 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%.

5. **Flex Studies**
   The following additional flex studies were performed with the Rightest Blood Glucose Monitoring System Max Tel: intermittent sampling, sample perturbation, drop and vibration, testing with used test strips and interruption of testing. The testing demonstrated that the device is robust to these conditions.

6. **Electromagnetic Compatibility (EMC) Testing**
   The sponsor provided documentation certifying that acceptable electrical safety and EMC testing was performed and the system was found to be compliant.

7. **Infection Control Studies**
   The Rightest Blood Glucose Monitoring System Max Tel is intended for single-patient use only. Disinfection efficacy testing on the external surface materials of the meter demonstrated complete inactivation of 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 550 cleaning and disinfection cycles using the CaviWipes Disinfecting Towelettes. 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 protocols and 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.