



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

I Background Information:

A 510(k) Number

K240637

B Applicant

Bionime Corporation

C Proprietary and Established Names

RIGHTTEST 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:

Modification to an existing device to expand the claimed glucose measuring range (from 50-550 mg/dL to 20-600 mg/dL) and add Long Term Evolution (LTE) network capabilities.

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 self-testing
- Single-patient use only
- 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.

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions

that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

V Substantial Equivalence Information:

A Predicate Device Name(s):

RIGHTTEST Blood Glucose Monitoring System Max Tel

B Predicate 510(k) Number(s):

K231192

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K240637</u>	<u>K231192</u>
Device Trade Name	RIGHTTEST Blood Glucose Monitoring System Max Tel	Same
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
General Device Characteristic Differences		
Measuring Range	20 - 600 mg/dL	50 - 550 mg/dL
Data Transmission	LTE network	N/A

VI Standards/Guidance Documents Referenced:

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- 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:

Previously established in K231192.

2. Linearity:

The linearity study provided in K231192 supports the sponsor's claimed glucose measurement range of 20 - 600 mg/dL.

The meter displays "LO" with glucose values below 20 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.

3. Analytical Specificity/Interference:

Previously established in K231192. The sponsor has included the following in the labeling: 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.
- Do not test your blood glucose during or soon after a xylose absorption test. Xylose in the blood can give inaccurate results with this meter.

4. Assay Reportable Range:

Glucose 20 - 600 mg/dL.

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

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 protocols and acceptance criteria were previously reviewed in K231192 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 39°F - 86°F (4°C - 30°C) and 10 - 90% relative humidity. The labeling instructs the users not to freeze the test strips.

6. Detection Limit:

The assay reportable range is 20 - 600 mg/dL.

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 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):

Accuracy at Extreme Glucose Values:

To supplement the previous accuracy performance studies conducted in K231192 and support the broader measuring range claim (from previously cleared 50-550 mg/dL in K231192 to 20-600 mg/dL) an additional extreme glucose study was performed using 113 capillary blood samples to assess the accuracy of the Rightest Blood Glucose Monitoring System Max Tel at the extreme glucose concentrations at the extreme lower and upper ends of the measuring range. Of the 113 samples, 72 were altered by glycolysis or spiking to achieve appropriate glucose concentrations to achieve 53 samples ranging from 20.4 to 77.4 mg/dL glucose and 60 samples with glucose concentrations ranging from 257 to 599 mg/dL (as measured by YSI 2300). Each sample was measured on the candidate device and results compared to results obtained on the YSI 2300 analyzer. Results are summarized in the table below:

For glucose concentrations < 80 mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
42/53 (79.2%)	50/53 (94.3%)	53/53 (100.0%)	53/53 (100.0%)
For glucose concentrations > 250 mg/dL			
Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
51/60 (85.0%)	59/60 (98.3%)	60/60 (100.0%)	56/60 (100.0%)

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

The sponsor includes the following in the labeling for 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:

Software and Cybersecurity:

The sponsor provided software and cybersecurity documentation that was reviewed and found to be acceptable.

Test Strip Lot Release:

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.