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

**A. 510(k) Number:**

k173139

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Glucose in capillary whole blood

**D. Type of Test:**

Quantitative, amperometric assay (Glucose Oxidase)

**E. Applicant:**

Bionime Corporation

**F. Proprietary and Established Names:**

Rightest Blood Glucose Monitoring System Wiz
Rightest Blood Glucose Monitoring System Wiz 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 indications for use below.

2. Indication(s) for use:

   **Rightest Blood Glucose Monitoring System Wiz**
   Rightest Blood Glucose Monitoring System Wiz 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 Wiz 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).

   Rightest Blood Glucose Test Strip Wiz is used with Rightest Wiz Blood Glucose Meter 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 Wiz Plus**
   Rightest Blood Glucose Monitoring System Wiz Plus 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 Wiz Plus 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).
   Rightest Blood Glucose Test Strip Wiz is used with Rightest Blood Glucose Meter Wiz Plus 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):

   The following are included in the labeling for both the Rightest Blood Glucose Monitoring System Wiz and the Rightest Blood Glucose Monitoring System Wiz Plus

Systems:

- Intended for self-testing.
- Can only use with capillary whole blood samples.
- For over the counter use and single patient use only.
- Not be used for the diagnosis of, or screening for diabetes
- It is not for use on critically ill patients, it is not for use on neonates either.
- The 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.
- 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).
- Patients going through oxygen therapy may yield falsely low results
- Do not use at altitudes greater than 10,000 feet (3,048 meters).
- Hematocrit levels outside the 20-60% range may yield inaccurate results. If you are unsure of your hematocrit value please discuss with your health care professional.
- Do not test the blood sample from palm or forearm when glucose is changing rapidly (senarios: after drinking, after meal, after exercise).
- Do not test on the palm or forearm if you are testing for insulin dose calculations or hypoglycemia (Low blood glucose).
- Do not use the test results from alternative site testing (palm, forearm) to calibrate Continuous Glucose Monitoring (CGM) devices.

4. Special instrument requirements:

   Rightest Blood Glucose Monitoring System Wiz
   Rightest Blood Glucose Monitoring System Wiz Plus

## I. Device Description:

Rightest BGMS Wiz and Wiz Plus are identical with the exception that the Wiz Plus has a Bluetooth function which allows for wireless information transfer. Rightest BMGS Wiz/Wiz Plus systems consists of the Rightest Wiz/Wiz Plus Blood Glucose Meter, the Rightest Blood Glucose Test Strip Wiz (sold separately in boxes of 10 to 200 pcs), Rightest Control Solution GC550 (levels 1, 2 and 3), Lancing Device, Sterile Lancets and User Manual.

## J. Substantial Equivalence Information:

1. Predicate device name(s):

   Rightest Blood Glucose Monitoring System GM280B

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

   k170143

3. Comparison with predicate:

| Similarities | | | |
|---|---|---|---|
| Item | Candidate Device Rightest BGMS Wiz | Candidate Device Rightst BGMS Wiz Plus | Predicate Device Rightest Blood Glucose Monitoring System GM280B |
| 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 | Same |
| Measurement Technology | Glucose Oxidase Electrochemical Sensor | Same | Same |
| Minimum Sample Volume | 0.75 µl | Same | Same |
| Primary Site Testing | Fingertip | Same | Same |
| Alternative Site Testing | Forearm, palm | Same | Same |
| Measuring Range | 20-600 mg/dL | Same | Same |
| Test Time | 5 seconds | Same | Same |

| Differences | | | |
|---|---|---|---|
| Item | Device Rightest BGMS Wiz | Device Rightst BGMS Wiz Plus | Predicate |
| Memory Capacity | 1000 blood glucose test results with date and time | 1000 blood glucose test results with date and time | 500 blood glucose test results with date and time |
| Meter Dimension | 50.0 mm x 82.0 mm x 15.5 mm | 50.0 mm x 82.0 mm x 15.5 mm | 82mmx45mmx15.5mm |
| Wireless Module | no | Bluetooth | Bluetooth |

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

Self-Monitoring Blood Glucose Test Systems for Over-the-Counter-Use: Guidance for Industry and Food and Drug Administration Staff. Issued: October 11, 2016.
CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition (2005).
IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

## L. Test Principle:

The 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):

The only differences between the RIGHTEST Wiz and the RIGHTEST Wiz Plus Blood Glucose Monitoring Systems are the names of the systems and meters and the addition of a Bluetooth communication module to the RIGHTEST Wiz Plus meter. All performance evaluations below were performed using the RIGHTEST Wiz Plus system to represent both systems.

1. Analytical performance:

   a. *Precision/Reproducibility:*
   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 | 38.7 | 1.1 | 2.8 |
| | 2 | 38.6 | 1.2 | 3.0 |
| | 3 | 38.6 | 1.1 | 2.9 |
| 51-110 | 1 | 84.3 | 1.5 | 1.8 |
| | 2 | 84.8 | 1.9 | 2.3 |
| | 3 | 84.9 | 1.8 | 2.1 |
| 111-150 | 1 | 137.1 | 2.5 | 1.8 |
| | 2 | 136.0 | 2.7 | 2.0 |
| | 3 | 136.4 | 2.6 | 1.9 |
| 151-250 | 1 | 220.8 | 3.0 | 1.3 |
| | 2 | 221.7 | 3.0 | 1.4 |

| Glucose Level (mg/dL) | Lot | Mean (mg/dL) | SD (mg/dL) | CV (%) |
|---|---|---|---|---|
| | 3 | 221.1 | 3.2 | 1.5 |
| 251-400 | 1 | 330.6 | 4.7 | 1.4 |
| | 2 | 329.4 | 4.7 | 1.4 |
| | 3 | 329.7 | 4.5 | 1.4 |

Intermediate (between run) precision was evaluated using five 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 replicates 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 | 39.1 | 1.0 | 2.6 |
| | 2 | 39.0 | 1.0 | 2.6 |
| | 3 | 36.7 | 0.9 | 2.4 |
| 51-110 | 1 | 85.2 | 1.5 | 1.8 |
| | 2 | 84.3 | 1.5 | 1.8 |
| | 3 | 86.7 | 1.6 | 1.9 |
| 111-150 | 1 | 129.5 | 1.9 | 1.4 |
| | 2 | 129.9 | 1.8 | 1.4 |
| | 3 | 129.3 | 1.9 | 1.5 |
| 151-250 | 1 | 220.5 | 2.9 | 1.3 |
| | 2 | 220.3 | 2.7 | 1.2 |
| | 3 | 220.4 | 2.8 | 1.3 |
| 251-400 | 1 | 280.7 | 3.8 | 1.3 |
| | 2 | 280.7 | 4.1 | 1.5 |
| | 3 | 280.5 | 3.7 | 1.3 |

b. *Linearity/assay reportable range:*
Linearity was assessed with three lots of Blood Glucose Test Strip GS570. Each test strip lot was tested with three Rightest Blood Glucose Monitoring Systems Wiz Plus using blood samples spiked to 14 target analyte levels (18.6, 29.2, 62.8, 104.0, 160.5, 225.0, 277, 325.5, 365.5, 413, 449.5, 544, 569, 612.5 mg/dL). Each sample was measured in triplicate with each Rightest Blood Glucose Monitoring System GM570 and measured in duplicate with a laboratory-based comparator method (YSI 2300 glucose analyzer). The evaluation yielded the following regression equations for the three lots based on all samples:

Lot 1: $y = 0.9922x + 1.1243$, $R^2 = 0.9996$
Lot 2: $y = 0.9927x + 1.2096$, $R^2 = 0.9996$
Lot 3: $y = 0.9936x + 1.1132$, $R^2 = 0.9996$

Lots combined: $y = 0.9921x + 1.4666$, $R^2 = 0.9995$

The results of the study support the sponsor's claimed glucose measuring range of 20-600 mg/dL. The meter displays "Lo" with glucose values below 20mg/dL, and "HI" with glucose values over 600 mg/dL. The "Lo" and "Hi" functions were validated and demonstrated to function as intended.

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

*Traceability*
The Rightest Blood Glucose Monitoring System Wiz and Rightest Blood Glucose Monitoring System Wiz Plus traceable to the NIST SRM 917c glucose reference material.

*Test Strip Stability*
Test Strips are identical to the strip that were cleared in k170143. The claimed shelf life stability and open vial stability is 24 months from manufacture when stored at 40-86 °F (4-30 °C) and 10-90% relative humidity in k170143.

d. *Detection limit:*

See linearity in section M1b above.

e. *Analytical specificity:*

Interference was evaluated at three glucose concentration intervals (60-100, 100-150, and 250-300 mg/dL) by analyzing 26 potentially interfering exogenous and endogenous substances. Average glucose values measured with the Rightest Blood Glucose Monitoring System Wiz Plus in samples spiked with a potentially interfering substance were compared with average values measured in control samples (without potentially interfering substance) on the Rightest Blood Glucose Monitoring System Wiz Plus. The sponsor defined significant interference as bias greater than ±10% (vs control condition). The compounds at the concentrations listed below were the highest concentrations tested that did not demonstrate significant interference:

| Potential Interferent | Highest concentration tested at which no significant interference is observed (mg/dL) |
|---|---|
| Acetaminophen | 20 |
| Ascorbic Acid | 3 |
| Conjugated Bilirubin | 10 |
| Unconjugated Bilirubin | 50 |
| Cholesterol | 600 mg/dL |
| Creatinine | 10 |

| Potential Interferent | Highest concentration tested at which no significant interference is observed (mg/dL) |
|---|---|
| Dopamine | 1.6 |
| Galactose | 15 |
| Gentisic Acid | 6 |
| Glutathione Reduced | 25 |
| Hemoglobin | 20,000 |
| Ibuprofen | 50 |
| Icodextrin | 1,100 |
| L-dopa | 2 |
| Maltose | 10,000 |
| Methyldopa | 2 |
| Salicylic acid | 60 |
| Sodium Chloride | 1,052 |
| Tolazamide | 40 |
| Tolbutamide | 100 |
| Triglyceride | 1,500 |
| Uric acid | 11.8 |
| Xylose | 200 |
| Mannitol | 0.09 |
| Sorbitol | 0.09 |
| Xylitol | 0.09 |
| Lactitol | 0.09 |
| Isomalt | 0.09 |
| Maltitol | 0.09 |

Based on the 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 Bilirubin-conjugated level to increase more than 10 mg/dL, such as liver disease or jaundice, then the results from your meter may not be correct.
- If you have a condition that may cause your blood levels of uric acid to increase more than 11.8 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. See User Performance Studies below (section M.3.d) for demonstration of system accuracy in the hands of the intended user.

   b. *Matrix comparison:*

      Not applicable

3. Clinical studies:

   a. *Clinical Sensitivity:*

      Not applicable

   c. *Clinical specificity:*

      Not applicable

   d. *Other clinical supportive data (when a. and b. are not applicable):*

      **User Performance Studies**
      To assess system accuracy of the Rightest Blood Glucose Monitoring System Wiz Plus in the hands of the intended user, 357 lay users tested their own fingertip capillary blood samples along with palm and forearm samples. Results were compared to the measurements made using a laboratory-based comparator method (YSI 2300 analyzer). Samples ranged in glucose concentration from 50.8 - 543 mg/dL as measured by YSI comparator method. Results of the candidate meter relative to YSI are summarized below:

**Fingertip capillary samples with all glucose concentrations**

| Within ±5% | Within ±10 % | Within ±15 % | Within ±20% |
|---|---|---|---|
| 217/357 (61.1%) | 330/357 (92.4) | 357/357 (100.0%) | 357/357 (100.0%) |

**Palm capillary samples (AST) with all glucose concentrations**

| Within ±5% | Within ±10 % | Within ±15 % | Within ±20% |
|---|---|---|---|
| 197/357 (55.2%) | 326/357 (91.3%) | 357/357 (100.0%) | 357/357 (100.0%) |

**Forearm capillary samples (AST) with**

| Within ±5% | Within ±10 % | Within ±15 % | Within ±20% |
|---|---|---|---|
| 203/357 (56.9%) | 312/355 (87.4%) | 357/357 (100.0%) | 357/357 (100.0%) |

| Testing Site | Linear equation | $R^2$ |
|---|---|---|
| Fingertip | y = 1.00x + 1.94 | 0.99 |
| Palm | y = 1.02x + 0.71 | 0.99 |
| Forearm | y = 0.96x + 4.13 | 0.99 |

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

**Extreme Glucose Study**
Performance at extreme glucose levels was evaluated by measuring 58 samples with glucose concentrations below 80 mg/dL and 64 samples with glucose concentrations greater than 250 mg/dL on the Rightest Blood Glucose Monitoring System Wiz Plus. The meter values were compared to the comparator method values (YSI 2300 Plus Glucose Analyzer).

**Fingertip capillary samples with glucose concentrations <80 mg/dL**

| Within ±5% | Within ±10 % | Within ±15% | Within ±20% |
|---|---|---|---|
| 27/51 (53.0%) | 42/51 (82.4%) | 50/51 (98.0%) | 51/51 (100.0%) |

**Fingertip capillary samples with glucose concentrations >250 mg/dL**

| Within ±5% | Within ±10 % | Within ±15% | Within ±20% |
|---|---|---|---|
| 40/59 (67.8%) | 57/59 (96.6%) | 59/59 (100%) | 59/59 (100%) |

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   **Expected glucose values for persons without diabetes:**

| Status | Range |
|---|---|
| Before a meal | 80 - 130 mg/dL |
| Two hours after meals | Less than 180 mg/dL |

Checking Your Blood Glucose - What Are the Target Ranges? - American Diabetes Association (ADA)[Electronic Version] Retrieved Jun. 14, 2018 form http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucosecontrol/checking-your-blood-glucose.html

**N. Instrument Name:**

Rightest Blood Glucose Monitoring System Wiz Plus
Rightest Blood Blucose Monitoring System Wiz

**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?
   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 Blood Glucose Monitoring System Wiz Plus and Rightest Blood Glucose Monitoring System Wiz. 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 minimum sample volume of the blood glucose test strips, a study was performed using 3 lots of test strips, venous blood samples at 3 glucose concentrations (50-65 mg/dL, 100-120 mg/dL and 200-250 mg/dL) and the following 9 sample volumes; 0.60µL, 0.65µL, 0.70 µL, 0.75 µL, 0.80 µL, 1.00 µL, 1.25 µL, 2.00 µL and 3.00 µL. Test procedures were performed in 3 replicates, and results were compared to reference method YSI 2300 Analyzer. The study results supported the claimed minimum sample volume of 0.75 µL and that the sample volume detection feature functioned as intended.

2. **Altitude Study**
   To evaluate the effects of altitude on system performance, three test strip lots were tested with three meters using three venous blood samples with glucose concentration of 50-75mg/dL, 80-120 mg/dL and 270-330 mg/dL. The samples were tested at 0, 3281, 6562 and 9843 feet above sea leavel. 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 the system can be used at altitudes up to 10,000 ft. (3275 meters).

3. **Hematocrit Study**
   To evaluate the effect of different hematocrit levels on system performance, 10 meters were used to test venous blood with nine HCT levels of 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55% and 60%. HCT levels where tested over five glucose concentrations of 30-50mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL and 251-400 mg/dL. 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**
   To evaluate the effect of different environmental operating coditions on the system, three devices where tested at six different operating conditions. Three different temperatures ( 10-11ºC, 25±2ºC and 39-40ºC) each at two different relative humidity levels (10% and 90%). 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 devices are intended for a single-patient use only. Disinfection efficacy studies were performed on the materials comprising the outer meter, including polycarbonate and acrylonitirile butadiene styrene. The studies were conducted by an outside commercial testing laboratory demonstrating 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 external materials of the meter. The robustness studies were designed to simulate cleaning and disinfection procedure twice a week for five years for a total of 520 cycles. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

**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.