

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

A. 510(k) Number:

K042678

B. Purpose for Submission:

New Device

C. Measurand:

Glucose

D. Type of Test:

Quantitative Amperometric Assay (Glucose Oxidase)

E. Applicant:

Bionime Corporation

F. Proprietary and Established Names:

Rightest Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1345, Glucose Test System

21 CFR § 862.1660, Quality Control Material, Assayed and Unassayed

2. Classification:

Class II (Glucose Test System)

Class I (Quality Control Material)

3. Product code:

NBW, CGA (Glucose Test System)

JJX (Quality Control Material)

4. Panel:

75 (Clinical Chemistry)

H. Intended Use:

1. Intended use / Indication(s) for use:

The Rightest Blood Glucose Monitoring System is intended for in vitro diagnostic use (outside of body). It is indicated to be used by professional healthcare personnel or diabetics at home to measure the glucose concentration for aiding diabetes management. The glucose concentration is measured using capillary whole blood from the fingertip by using Rightest Blood Glucose Monitoring System.

This test device is not intended for testing neonate blood samples.

2. Special conditions for use statement(s):
This device is intended for use with capillary whole blood but produces plasma equivalent results.
3. Special instrument requirements:
Bionime Corporation Rightest Blood Glucose Monitoring System

I. Device Description:

This device consists of the glucose meter itself, a Smart Code Key, test strips, control solutions, a check key, lancets, and labeling. To operate the meter, the user inserts a Smart Code Key that is included with each bottle of test strips. A numerical code appears on the display when the key is inserted. Once the user confirms that the numerical code on the display, the key, and the bottle of strips all match, they can insert a strip into the Smart Code Key and proceed with testing. The sponsor has provided instructions and illustrations explaining that the blood drop will be pulled into the strip sample entry by capillary action and that the view window must be completely filled with blood to get an accurate result. Results are stored in the meter's memory for future use.

The check key is used for testing the quality control solutions. The check key is inserted into the Smart Code Key to put the meter in "control" mode. Once the meter is in control mode, the user removes the check key, inserts a test strip, and proceeds to test a control solution as they would a blood sample. Control results are not stored in the meter's memory.

The lance supplied with this device was previously cleared under k833344. The two control solutions supplied with this device were previously cleared under k012430.

J. Substantial Equivalence Information:

1. Predicate device name(s):
ONE TOUCH ® Ultra ® Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
k024194
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection Method	Same	Amperometry
Enzyme	Same	Glucose Oxidase
Mediator	Same	Potassium Ferricyanide
Reportable Range	Same	20 - 600 mg/dL
Operating Temperature Range	10 - 40° C 50 - 104° F	6 - 44° C 43 - 111° F
Operating Humidity Range	Same	10 - 90 %
Strip Expiration After Opening	Same	3 months

Differences		
Item	Device	Predicate
Electrode	Noble Metal Electrode	Carbon Electrode
Time to Result	15 seconds	5 seconds
Sample Volume	2 µL	1 µL
Memory Capability	3, 7, and 14 day average; last 200 tests in memory	14 day average; last 150 tests in memory

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

NCCLS EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices

NCCLS EP6-A: Evaluation of the Linearity of Quantitative Analytical Methods

NCCLS EP7-A: Interference Testing in Clinical Chemistry

NCCLS EP9-A2: Method Comparison and Bias Estimation Using Patient Samples

EN 60601-1-2: (2001): Medical electrical equipment Part 1-2: General requirements for safety Collateral standard: Electromagnetic compatibility Requirements and tests-Edition 2.1; Edition 2:2001 consolidated with amendment 1:2004

EN 61000-4-2: (1995): Electromagnetic Compatibility (EMC) - Part 4-2: Testing and Measurement Techniques - Electrostatic Discharge Immunity Test-Edition 1.2

EN 61000-4-3: (1999): Electromagnetic Compatibility (EMC) - Part 4-3: Testing and Measurement Techniques - Radiated, Radio-Frequency, Electromagnetic Field Immunity Test

CISPR 11: (1997): Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment - Electromagnetic Disturbance Characteristics - Limits and Methods of Measurement

L. Test Principle:

The glucose oxidase and potassium ferrocyanide in the strip react with the glucose in the sample to produce 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.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The sponsor evaluated the precision of the device using replicate measurements of glucose control solutions and anticoagulated venous whole blood.

The glucose control solutions 1 - 5 had concentrations of approximately 82, 103, 156, 227, and 395 mg/dL. The protocol used two lots of test strips, five Bionime glucose meters, and one operator. Each solution was analyzed in duplicate over 20 consecutive days and for two lots of test strips, for a total of 80 measurements per meter per level. The results for the control solutions were as follows:

Control Soln 1	Meter #1	Meter #2	Meter #3	Meter #4	Meter #5
Mean (mg/dL)	81	82	82	82	81
Within-Run Imprecision (SD)	2.3	2.6	1.5	2.2	1.9
Between-Run Imprecision (SD)	1.1	2.0	0.6	1.6	1.2
Total Imprecision (SD)	2.9	2.8	2.6	2.6	2.6
*Coefficient of Variation (%)	3.6	3.4	3.1	3.2	3.2

Control Soln 2	Meter #1	Meter #2	Meter #3	Meter #4	Meter #5
Mean (mg/dL)	102	103	103	102	103
Within-Run Imprecision (SD)	1.9	1.7	1.4	1.7	1.6
Between-Run Imprecision (SD)	1.0	1.1	0.8	0.7	0.9
Total Imprecision (SD)	2.6	2.1	1.7	2.3	2.1
*Coefficient of Variation (%)	2.5	2.0	1.6	2.2	2.0

Control Soln 3	Meter #1	Meter #2	Meter #3	Meter #4	Meter #5
Mean (mg/dL)	156	156	156	156	154
Within-Run Imprecision (SD)	3.6	2.6	2.6	3.7	3.7
Between-Run Imprecision (SD)	2.7	1.5	1.1	3.0	2.9
Total Imprecision (SD)	3.6	3.5	3.5	3.8	4.0
*Coefficient of Variation (%)	2.3	2.2	2.2	2.5	2.6

Control Soln 4	Meter #1	Meter #2	Meter #3	Meter #4	Meter #5
Mean (mg/dL)	229	227	228	227	225
Within-Run Imprecision (SD)	4.6	3.1	4.4	4.7	5.4
Between-Run Imprecision (SD)	3.4	2.1	1.0	2.1	2.9
Total Imprecision (SD)	5.0	4.9	6.5	6.2	6.5
*Coefficient of Variation (%)	2.2	2.2	2.8	2.7	2.9

Control Soln 5	Meter #1	Meter #2	Meter #3	Meter #4	Meter #5
Mean (mg/dL)	397	396	396	395	394
Within-Run Imprecision (SD)	10.3	11.2	9.1	8.5	8.6
Between-Run Imprecision (SD)	8.8	9.9	2.6	6.1	4.7
Total Imprecision (SD)	11.3	10.6	12.3	10.2	11.8
*Coefficient of Variation (%)	2.8	2.7	3.1	2.6	3.0

*Coefficient of variation = (total imprecision SD/mean) X 100

The venous whole blood samples had concentrations of approximately 100, 200, and 353 mg/dL. The protocol used two lots of test strips, five Bionime glucose meters, and one operator. Each solution was analyzed five times over six hours using two lots of test strips, for a total of 10 measurements per meter per level. The results for the venous whole blood samples were as follows:

WB - Normal	Meter #1	Meter #2	Meter #3	Meter #4	Meter #5
Mean	100	100	100	99	99
Standard Deviation	3	4	3	2	3
Coefficient of Variation (%)	3.2	3.9	2.5	2.4	3.4

WB – Mid	Meter #1	Meter #2	Meter #3	Meter #4	Meter #5
Mean	199	203	198	202	200
Standard Deviation	6	5	4	6	5
Coefficient of Variation (%)	2.9	2.2	2.1	3.1	2.6

WB – High	Meter #1	Meter #2	Meter #3	Meter #4	Meter #5
Mean	353	346	354	354	357
Standard Deviation	7	12	13	10	4
Coefficient of Variation (%)	2.0	3.5	3.7	2.7	1.1

b. Linearity/assay reportable range:

The linearity of the device was demonstrated by comparing eleven prepared whole blood samples on the Rightest and a glucose reference method. The eleven equally spaced samples ranged in concentration from a low of approximately 50 mg/dL to a high of approximately 550 mg/dL. Linear regression of the comparison data yielded the following relationship:

$$\text{Rightest} = (1.02 \times \text{Reference Method}) - 15 \text{ mg/dL}$$

$$r^2 = 0.9957$$

The reportable range of the Rightest meter is 20 - 600 mg/dL

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

The controls supplied with this device were previously cleared under k012431. The sponsor has shown traceability of the Rightest meter to a

laboratory analyzer.

d. *Detection limit:*

20 mg/dL

e. *Analytical specificity:*

The specificity of the device was assessed by preparing five venous whole blood samples ranging in concentration from approximately 50 - 300 mg/dL. The five samples were divided into aliquots and spiked with twenty potential interferents, including endogenous and exogenous substances, anticoagulants, and preservatives. This was designated the test sample. A control sample was also prepared, which consisted of the venous whole blood sample and the solvent for the interferent, but not the interferent itself. The difference between the control sample and the test sample was considered to be due to the interferent, as summarized in the table below:

Interferent (concentration)	Effect (test vs. control sample)
Acetaminophen (3 mg/dL)	Less than 10% at all 5 concentrations
Ascorbic Acid (4 mg/dL)	Plus 10% at 130 mg/dL Less than 10% at all other concentrations
Dopamine HCl (0.11 mg/dL)	Less than 10% at all 5 concentrations
Ibuprofen (50 mg/dL)	Less than 10% at all 5 concentrations
L-Dopa (1.5 mg/dL)	Plus 15% at 61 mg/dL Plus 14% at 83 mg/dL Less than 10% at all other concentrations
Methyldopa (1.5 mg/dL)	Plus 17% at 63 mg/dL Less than 10% at all other concentrations
Salicylic Acid (20 mg/dL)	Less than 10% at all 5 concentrations
Tetracycline (1.5 mg/dL)	Less than 10% at all 5 concentrations
Tolbutamide (65 mg/dL)	Less than 10% at all 5 concentrations
Conjugated Bilirubin (5 mg/dL)	Less than 10% at all 5 concentrations
Cholesterol (250 mg/dL)	Minus 17% at 76 mg/dL Minus 12 % at 111 mg/dL Less than 10% at all other concentrations
Creatinine (6.61 mg/dL)	Less than 10% at all 5 concentrations
Triglyceride (500 mg/dL)	Plus 10% at 135 mg/dL Plus 22% at 188 mg/dL Plus 19% at 298 mg/dL; Less than 10% at all other concentrations
Uric Acid (9 mg/dL)	Plus 25% at 65 mg/dL Plus 24% at 85 mg/dL Plus 10% at 114 mg/dL Plus 13% at 158 mg/dL Plus 10% at 237 mg/dL
EDTA (200 mg/dL)	Less than 10% at all 5 concentrations
Trisodium citrate dihydrate (320 mg/dL)	Less than 10% at all 5 concentrations
Lithium Heparin (20 mg/dL)	Less than 10% at all 5 concentrations
Sodium Heparin (20 mg/dL)	Less than 10% at all 5 concentrations
Sodium Fluoride (200 mg/dL)	Plus 12 % at 170 mg/dL Plus 10% at 249 mg/dL Less than 10% at all other concentrations
Potassium Oxalate (200 mg/dL)	Less than 10% at all 5 concentrations

f. *Assay cut-off:*
Not Applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor did two method comparison studies. The first was done in a point of care (POC) setting to demonstrate the accuracy of the device when used by POC personnel. The second study enrolled consumers to determine if they could perform the test accurately using only the labeling provided with the product.

Point of Care Study. This study included paired whole blood and plasma samples from 309 individuals and included glucose concentrations from 68 - 565 mg/dL. The whole blood samples were analyzed on the Rightest meter by POC personnel and the plasma samples were analyzed on a laboratory instrument. Linear regression of the data yielded the following equation:

$$\text{Rightest} = (1.00 \times \text{Laboratory Method}) + 5 \text{ mg/dL} \\ r^2 = 0.9773$$

Consumer Study. This study included paired whole blood and plasma samples from 128 consumers as they presented themselves at a physician's office or an outpatient clinic. The consumers collected and analyzed their own capillary blood sample and the plasma samples were analyzed on a laboratory instrument. Linear regression of the data yielded the following equation:

$$\text{Rightest} = (1.00 \times \text{Laboratory Method}) + 5 \text{ mg/dL} \\ r^2 = 0.9851$$

b. *Matrix comparison:*

Not Applicable. This device is intended to be used with capillary whole blood from the finger only.

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):

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

The sponsor included the following Expected Values in their labeling:

Time	Range (mg/dL)	Range (mmol/L)
Fast for 8 hours:		
Pre-diabetes	100 - 125	5.6 - 6.9
Diabetes	>126	>7.0
After eating or oral glucose tolerance test:		
Pre-diabetes	140 - 199	7.8 - 11.1
Diabetes	>200	>11.1

The sponsor's bibliography indicates that this information is taken from the American Diabetes Association website

N. Instrument Name:

Bionime Corporation Rightest Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional readings.

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:

This device is intended to be used with capillary whole blood from the finger only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

A Smart Code Key is provided with each batch of test strips to calibrate the meter for that batch. No further calibrations are required of the user.

6. Quality Control:

The sponsor is providing a high and low glucose control solution with this device. When the Check Key is inserted into the meter, the control mode is activated. This prevents control results from being stored in the internal memory. An acceptable range for each control level is printed on the test strip vial label. The user is referred to the troubleshooting section of the User's Manual if control results fall outside these ranges.

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

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.