

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

A. 510(k) Number:

k053635

B. Purpose for Submission:

Change to labeling and modified indications for use.

C. Measurand:

Glucose

D. Type of Test:

Blood Glucose Concentration through a 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
2. Classification:
Class II
3. Product code:
NBW, CGA
4. Panel:
75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):
See Indications for use.
2. 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 with quantitative capillary whole blood from the fingertip, palm, and forearm by using Rightest Blood Glucose Monitoring System. This device is not intended for testing neonate blood samples.
3. Special conditions for use statement(s):
Rightest System provides plasma equivalent results.
4. Special instrument requirements:
Bionime Corporation Rightest Blood Glucose Monitoring System.

I. Device Description:

The Rightest Blood Glucose Monitoring System includes Meter, Blood Glucose Test Strips, Code Key, Check Key, Two Control Solutions, Lancing Device and lancets. The Rightest meter, Blood Glucose Test Strips, Code Key, and Check Key are manufactured by Bionime Corporation. The Rightest Meter, when used with the Rightest Test Strips Blood Glucose Test Strips, quantitatively measures glucose in fresh capillary whole blood.

The performance of the Rightest Blood Glucose Test Strips is verified by Control Solutions. The Check Key verifies the status of the Rightest meter. For a more detailed description, see k042678.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Rightest Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
K042678
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Mediator	Potassium ferricyanide	Potassium ferricyanide
Test Range	20 – 600 mg/dL	20 – 600 mg/dL
Hematocrit Range	30-55%	30-55%
Temperature Range	50-104°F, 10-40°C	50-104°F, 10-40°C
Humidity Range	10-90%	10-90%
Warranty (meter)	3 years	3 years
Open Use Time (strip)	3 months	3 months
Electrode	Noble metal electrode	Noble metal electrode
Coding	Code key	Code key
Test Time	15 seconds	15 seconds
Sample Volume	2 µL	2 µL
Memory Capability	3, 7, 14 day average and last 200 tests in the memory	3, 7, 14 day average and last 200 tests in the memory
Power	1.5Vx2 battery (LR03)	1.5Vx2 battery (LR03)
Battery Life	Running 1,500 test	Running 1,500 test

Differences		
Item	Device	Predicate
Sample Source	The glucose concentration is measured with quantitative capillary whole blood from the fingertip, palm, and forearm by using the Rightest Blood Glucose Monitoring System.	The glucose concentration is measured with quantitative capillary whole blood from the fingertip by using the Rightest Blood Glucose Monitoring System.
Description and Labeling	Alternate site testing (AST) information listed in the user's manual and packaging.	No information listed.

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

See k042678 for more information.

L. Test Principle:

The glucose oxidase and potassium ferricyanide 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. See k042678 for more information.

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. For a more detailed description, see k042678.

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. For a more detailed description, see k042678.

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. For a more detailed description, see k042678.

d. *Detection limit:*

20 mg/dL. For a more detailed description, see k042678.

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. For a more detailed description of the interference results, see k042678.

f. *Assay cut-off:*

Not Applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor did two method comparison studies. The first study compared capillary blood from finger, palm, and forearm tested by a technician on the Rightest Blood Glucose Monitoring System and comparing each test to the blood drawn from the same areas and analyzed on YSI 2300D for each patient. The second study compared capillary blood from finger, palm, and forearm tested by the patient on the Rightest Blood Glucose Monitoring System and comparing each test to the blood drawn from the same areas and analyzed on YSI 2300D. All patients blood glucose levels were in a steady state for these studies. The two studies are summarized below:

Technician	Rightest fingerstick vs YSI-Plasma	Rightest palmstick vs YSI-Plasma	Rightest armstick vs YSI-Plasma
Test Range	55.7~490 mg/dL		
Test Number	134	134	132
Slope	1.03	1.02	0.96
Intercept	-1.63	1.18	6.55
r	0.9852	0.9862	0.9793

Error Grid Analysis (EGA)			
A zone	97.0%	96.3%	96.2%
B zone	3.0%	3.7%	3.8%
C zone	0%	0%	0%

Patient	Rightest fingerstick vs YSI-Plasma	Rightest palmstick vs YSI-Plasma	Rightest armstick vs YSI-Plasma
Test Range	55.7~490 mg/dL		
Test Number	134	133	132
Slope	1.06	1.03	0.99
Intercept	-4.15	-0.32	3.10
r	0.9865	0.9874	0.9829

Error Grid Analysis (EGA)			
A zone	95.5%	97.0%	96.2%
B zone	4.5%	3.0%	3.8%
C zone	0%	0%	0%

b. Matrix comparison:

See above: *Method comparison with predicate device*

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 for normal glucose levels in their strip labeling:

Status	Range (mg/dL)	Range (mmol/L)
Fasting	70-99	3.9-5.5

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 See k042678 for more information.

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, palm, or forearm 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.

