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

A. 510(k) Number:
k062567

B. Purpose for Submission:
Modification of some operating characteristics of a previously cleared device (see J. 3 below).

C. Measurand:
Glucose

D. Type of Test:
Quantitative Amperometric Assay (Glucose Oxidase)

E. Applicant:
Bionime Corporation

F. Proprietary and Established Names:
Bionime 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:
   Clinical Chemistry (75)

H. Intended Use:
1. Intended use(s):
   See Indications for use below.
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.

   Special conditions for use statement(s): Rightest System provides plasma equivalent

results.

3. Special conditions for use statement(s):
   This device is not intended for testing neonate blood samples.

   The alternative site testing (palm and forearm) in the Rightest Blood Glucose Monitoring System can be used only during steady-state blood glucose conditions.

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 – original clearance
   k053635 – alternate test sites added
3. Comparison with predicate:
   The proposed device and its indications for use are the same as the predicate as cleared in k053635 except for the following modifications to the operating characteristics:

Differences		
Item	Device	Predicate
Sample Volume	1.4 ul	2 ul
Test Time	8 seconds	15 seconds
Measurement Unit	mg/dL	mg/dL or mmol/L
Memory Capability	300 tests; 1, 7, 14, 30 day averages	200 tests; 3, 7, 14 day averages
Battery Life	~1000 tests	~1500 tests

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

CLSI EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices
CLSI EP6-A: Evaluation of the Linearity of Quantitative Analytical Methods
CLSI EP7-A: Interference Testing in Clinical Chemistry
CLSI 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.

M. Performance Characteristics (if/when applicable):
1. Analytical performance:
   a. *Precision/Reproducibility:*
      Within-day precision:
      Venous blood samples were allowed to glycolyze or were spiked to five concentrations. Each sample was tested ten times by three different meters; one strip lot was tested. Testing results are summarized in the table below:

Bionime Rightest: Within-day Precision

Level 1	Meter 1	Meter 2	Meter 3
Mean	38 mg/dL	37.8 mg/dL	38 mg/dL
SD	1.3	1.3	1.1
CV	3.5 %	3.5 %	2.8 %
Level 2	Meter 1	Meter 2	Meter 3
Mean	111.1 mg/dL	108.2 mg/dL	110.8 mg/dL
SD	3.0	2.6	3.0
CV	2.7 %	2.4 %	2.8 %
Level 3	Meter 1	Meter 2	Meter 3

Mean	237.8 mg/dL	239.3 mg/dL	239 mg/dL
SD	4.3	4.7	6.6
CV	1.8 %	2.0 %	2.7 %
Level 4	**Meter 1**	**Meter 2**	**Meter 3**
Mean	369.7 mg/dL	367.5 mg/dL	371.8 mg/dL
SD	9.2	9.1	8.3
CV	2.5 %	2.5 %	2.2 %
Level 5	**Meter 1**	**Meter 2**	**Meter 3**
Mean	544.6 mg/dL	546.2 mg/dL	549.1 mg/dL
SD	11.6	11.0	9.5
CV	2.1 %	2.0 %	1.7 %

Five levels of control materials over the claimed assay range were used to establish total precision of the assay. Each solution was analyzed on five Bionime glucose meters by one operator in duplicate over 20 consecutive days using two lots of test strips, for a total of 80 measurements per meter per level per meter:

Control P-01	**YSI**	**Rightest #1**	**Rightest #2**	**Rightest #3**	**Rightest #4**	**Rightest #5**
Mean glucose (mg/dL)	58.5	55.1	56.0	56.1	55.9	56.1
Std Dev	1.26	2.01	1.70	1.57	2.01	2.11
% CV	2.15%	3.65%	3.04%	2.80%	3.60%	3.76%

Control P-02	**YSI**	**Rightest #1**	**Rightest #2**	**Rightest #3**	**Rightest #4**	**Rightest #5**
Mean glucose (mg/dL)	98.3	95.7	96.4	96.1	95.8	95.4
Std Dev	1.93	2.11	2.27	2.18	2.25	1.86
% CV	1.96%	2.20%	2.35%	2.27%	2.35%	1.95%

Control P-03	**YSI**	**Rightest #1**	**Rightest #2**	**Rightest #3**	**Rightest #4**	**Rightest #5**
Mean glucose (mg/dL)	137.2	134.8	136.1	136.3	135.7	135.8
Std Dev	2.67	3.19	2.76	2.96	3.06	3.59
% CV	1.95%	2.37%	2.03%	2.17%	2.24%	2.64%

Control P-04	**YSI**	**Rightest #1**	**Rightest #2**	**Rightest #3**	**Rightest #4**	**Rightest #5**
Mean glucose (mg/dL)	232.2	230.3	231.0	232.2	230.1	229.9

Std Dev	4.43	6.18	5.48	5.27	5.79	6.81
% CV	1.91%	2.68%	2.37%	2.27%	2.52%	2.96%

Control P-05	YSI	Rightest #1	Rightest #2	Rightest #3	Rightest #4	Rightest #5
Mean glucose (mg/dL)	382.2	381.3	381.6	382.7	380.1	380.6
Std Dev	7.59	8.13	9.65	7.45	9.61	9.31
CV	1.99%	2.10%	2.52%	1.95%	2.53%	2.45%

b. *Linearity/assay reportable range:*
The linearity of the device was demonstrated by comparing 15 prepared whole blood samples on the Rightest and a glucose reference method; each level was tested in quadruplicate by two lots of test strips. The 15 samples covered the claimed clinical of the meter. Analysis of the results showed a linear relationship between the Rightest and the YSI method: Lot 1 $y = 0.981x - 2.27$, $R^2 = 0.999$, Lot 2 $y = 0.981x – 1.79$, $R^2 = 0.999$. The reportable range of the Rightest meter is 20 - 600 mg/dL.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The control materials supplied for this device were cleared under k012431. The sponsor established traceability to a reference method in k042678.

d. *Detection limit:*
20 mg/dL: see linearity studies above. For values below 20 mg/dL the meter reads 'LO".

e. *Analytical specificity:*
The specificity of the device was established in k042678.

f. *Assay cut-off:*
Not applicable

2. Comparison studies:
   a. *Method comparison with predicate device:*
   A consumer study was performed with 176 lay-users and a technician to see if glucose readings from the forearm, palm and fingertip were comparable to a laboratory glucose reference method. The subjects ranged in age, education, and were about equally divided between males and females; the majority of the participants had Type II diabetes. The study was performed in a clinic setting. Patients sampled all three sites then the technician tested at all three sites and collected a venous blood specimen for measurement on a YSI analyzer. Each participant performed their own fingerstick and tested their blood using the instructions in the User's Guide. Samples ranged from 30 – 572 mg/dL. Linear regression analysis of the data yielded the results below:

Patient	Fingerstick vs. YSI	Palmstick vs. YSI	Armstick vs. YSI
n =	176	175	174
Regression	y = 1.03x – 0.25	y = 1.02x + 1.19	y = 1.02x – 0.84
r value	0.991	0.991	0.991
		System Accuracy	
Samples < 75 mg/dL within ±15 mg/dL YSI	27/28 (96%)	28/28 (100%)	28/28 (100%)
Samples ≥ 75 mg/dL within ± 20% YSI	143/148 (97%)	143/147 (97%)	142/146 (97%)

Technician	Fingerstick vs. YSI	Palmstick vs. YSI	Armstick vs. YSI
n =	176	176	174
Regression	y = 0.99x + 2.51	y = 1.01x + 1.70	y = 0.99x + 2.21
r value	0.991	0.991	0.988
		System Accuracy	
Samples < 75 mg/dL within ±15 mg/dL YSI	27/28 (96%)	27/28 (96%)	28/28 (100%)
Samples ≥ 75 mg/dL within ± 20% YSI	145/148 (98%)	144/148 (97%)	141/146 (96%)

An additional smaller study was done with 40 patients to evaluate the labeling materials. Results are summarized below:

Patient	Rightest *fingerstick* vs YSI-Plasma	Rightest *palmstick* vs YSI-Plasma	Rightest *armstick* vs YSI-Plasma
Test range		73 ~ 355	
Test number	42	42	42
Slope	1.03	1.05	1.03
Intercept	-5.59	-6.30	-4.39
r	0.9852	0.9860	0.9874

b. *Matrix comparison:*
   This system is cleared for use with fingerstick, palmstick, and armstick capillary samples. The meter's software adjusts the whole-blood glucose reading to a plasma-equivalent reading.

3. Clinical studies:

> a. *Clinical Sensitivity:*
> See method comparison section above.
> 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 normal fasting adult glucose range for a non-diabetic is 70 – 105 mg/dL. One to two hours after a meal, normal blood glucose levels should be less than 140 mg/dL. A medical professional should determine the range that is appropriate for diabetes patients.

N. Instrument Name:
Bionime 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:
Not applicable.

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.