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

A. 510(k) Number:
k072054

B. Purpose for Submission:
Modification to the device to reduce the read time and required sample volume of the GM300 meter

C. Measurand:
Whole blood 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 (GM310)

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 people with diabetes at home to measure the glucose concentration for aiding diabetes management. The glucose concentration is measured with quantitative capillary whole blood from fingertip, palm and forearm by using Rightest Blood Glucose Monitoring System. This test 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.

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: palm and forearm
   k062567 – change in read time, volume, and memory capacity

3. Comparison with predicate:

Similarities		
Item	Subject Device	Predicate Device(s)
Detection method	Amperometry	Amperometry
Enzyme	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Mediator	Potassium ferricyanide	Potassium ferricyanide
Sample Source	The glucose concentration is measured with quantitative capillary whole blood from the fingertip, palm and forearm by using Rightest Blood Glucose Monitoring System.	The glucose concentration is measured with quantitative capillary whole blood from the fingertip, palm and forearm by using Rightest Blood Glucose Monitoring System.
Test range	20 – 600 mg/dL	20 – 600 mg/dL
Memory capability	1, 7, 14, 30 day average and last 300 tests in the memory	1, 7, 14, 30 day average and last 300 tests in the memory
Battery life	Running 1,000 test	Running 1,000 test
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
Power	1.5V×2 battery (LR03)	1.5V×2 battery (LR03)

Differences		
Item	Subject Device (Sample Volume/Reaction Time)	Predicate Device(s)
Test Time	5 seconds	8 seconds
Sample Volume	0.6 uL	1.4 uL

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

CLSI EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices
ISO 14971: Application of risk management to medical devices
ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

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:

   Precision was performed using CLSI EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices. Three levels of samples were used to establish precision of the assay on blood samples. Each sample was analyzed on 5 Bionime glucose meters with each meter tested 10 times, for a total of 50 measurements:

Blood Sample	1	2	3
N	50	50	50
Mean (mg/dL)	91.9	197.5	356.4
SD (mg/dL)	1.7	3.2	5.8
%CV	1.8	1.6	1.6

Five levels of control materials over the claimed assay range were used to establish total precision of the assay. Each control solution was analyzed on 5 Bionime glucose

meters by one operator in duplicate over 20 consecutive days using two lots of test strips, for a total of 400 measurements:

Control Solution	1	2	3	4	5
N	400	400	400	400	400
Mean (mg/dL)	53	92	125	203	360
SD (mg/dL)	1.3	1.8	2.3	3.7	6.2
%CV	2.5	1.9	1.9	1.8	1.7

b. *Linearity/assay reportable range:*
The linearity of the device was demonstrated by comparing 14 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 14 samples covered the claimed clinical range of the meter (23.5 – 570 mg/dL). Analysis of the results showed a linear relationship between the Rightest and the reference method: Lot 1 $y = 0.987x – 4.2$, $R^2 = 0.999$, Lot 2 $y = 0.987x – 4.9$, $R^2 = 0.999$. 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 sponsor tested the following exogenous and endogenous substances for interference using two levels of glucose. The results are summarized below:

Interferant	Amount (mg/dL)		Normal Glucose Level		High Glucose Level	
			Control	Test	Control	Test
Exogenous						
Acetaminophen	3	Mean (mg/dL)	91.4	94.6	321	330.4
		Interferance	3.5%		2.9%	
Ascorbic Acid	4	Mean (mg/dL)	88.2	96	331	338.2
		Interferance	8.8%		2.2%	
Dopamine	0.11	Mean (mg/dL)	86.8	87.6	310.4	309.4
		Interferance	0.9%		-0.3%	
Ibuprofen	50	Mean (mg/dL)	85.8	88.2	324	328.8
		Interferance	2.8%		1.5%	
L-Dopa	1.5	Mean (mg/dL)	83.8	91.8	311.8	321.4
		Interferance	9.5%		3.1%	
Methyldopa	1.5	Mean (mg/dL)	89.2	92.8	356.4	362.6
		Interferance	4.0%		1.7%	
Salicylic Acid	20	Mean (mg/dL)	95.4	95.2	371.2	373.2
		Interferance	-0.2%		0.5%	
Tetracycline	1.5	Mean (mg/dL)	87.8	91	356.8	359.6
		Interferance	3.6%		0.8%	
Tolbutamide	65	Mean (mg/dL)	88.2	84.6	357.4	356.6
		Interferance	-4.1%		-0.2%	
Endogenous						
Bilirubin-conjugated	5	Mean (mg/dL)	88.6	89.2	357.6	357
		Interferance	0.7%		-0.2%	
Cholesterol	500	Mean (mg/dL)	92.6	77.4	358	341.4
		Interferance	-16.4%		-4.6%	
Creatinine	6.61	Mean (mg/dL)	88	87	361	359.6
		Interferance	-1.1%		-0.4%	
Triglycerides	500	Mean (mg/dL)	92	86.6	357.6	351.8
		Interferance	-5.9%		-1.6%	
Uric acid	9	Mean (mg/dL)	88.2	104.8	354.4	379.4
		Interferance	18.8%		7.1%	
Anticoagulants						
EDTA	100	Mean (mg/dL)	88.6	89.6	371	373
		Interferance	1.1%		0.5%	
Citrate	320	Mean (mg/dL)	86.4	90.2	352	355.8
		Interferance	4.4%		1.1%	
Li-Heparin	20	Mean (mg/dL)	90.2	89.4	367.2	368.6
		Interferance	-0.9%		0.4%	
Na-Heparin	20	Mean (mg/dL)	88.8	90.2	347.4	351
		Interferance	1.6%		1.0%	
Sodium Fluoride	200	Mean (mg/dL)	86.8	88	354.4	358.2
		Interferance	1.4%		1.1%	
Potassium oxalate/Ammonium oxalate	200	Mean (mg/dL)	92.2	95.6	347.2	350.8
		Interferance	3.7%		1.0%	
Saccharides						
Maltose	50	Mean (mg/dL)	87.2	88	347.2	350.8
		Interferance	0.9%		1.0%	
Xylose	100	Mean (mg/dL)	88	87	334.2	331.8
		Interferance	-1.1%		-0.7%	
Galactose	50	Mean (mg/dL)	83	83.6	349.4	353.6
		Interferance	0.7%		1.2%	
Lactose	50	Mean (mg/dL)	87	89.2	344	349.6
		Interferance	2.5%		1.6%	

The sponsor evaluated the effect of hematocrit levels 20 – 70% on whole blood samples spiked with eight hematocrit levels for three levels of glucose (low (40-70 mg/dL), medium (110-200 mg/dL) and high (200-400mg/dL). The values generated were compared with the glucose values from a reference method. Based on the deviation for glucose concentrations versus 40% hematocrit, the data supports the sponsor's claimed range of hematocrit levels between 30-55%. The results are summarized below.

0.6 µL-GM310						
Label #	Prepared venous blood					Plasma
	Mean	SD	CV	Bias vs YSI	Bias vs HCT 40%	YSI
Low Range of Glucose						
L-20	58.8	1.5	2.5%	12.4%	10.9%	52.3
L-25	55.8	1.3	2.3%	8.3%	5.3%	51.5
L-30	57.0	1.6	2.8%	8.4%	7.5%	52.6
L-40	53.0	1.6	3.0%	4.5%	0.0%	50.7
L-50	50.6	1.5	3.0%	-5.2%	-4.5%	53.4
L-55	48.0	1.6	3.3%	-7.2%	-9.4%	51.7
L-60	49.0	1.6	3.2%	-9.1%	-7.5%	53.9
L-70	45.8	1.5	3.2%	-8.8%	-13.6%	50.2
Normal Range of Glucose						
N-20	211.4	3.2	1.5%	22.9%	20.3%	172
N-25	197.6	3.7	1.9%	10.4%	12.4%	179
N-30	190.2	4.9	2.6%	8.1%	8.2%	176
N-40	175.8	3.1	1.8%	1.0%	0.0%	174
N-50	160.2	3.1	1.9%	-5.8%	-8.9%	170
N-55	154.8	3.6	2.3%	-8.4%	-11.9%	169
N-60	152.8	2.4	1.6%	-11.7%	-13.1%	173
N-70	143.4	3.6	2.5%	-18.1%	-18.4%	175
High Range of Glucose						
H-20	424.0	7.7	1.8%	17.5%	17.4%	361
H-25	410.2	7.6	1.8%	16.5%	13.6%	352
H-30	394.2	6.4	1.6%	8.3%	9.1%	364
H-40	361.2	5.4	1.5%	1.2%	0.0%	357
H-50	331.0	8.0	2.4%	-9.3%	-8.4%	365
H-55	321.6	3.2	1.0%	-10.4%	-11.0%	359
H-60	320.8	4.8	1.5%	-9.6%	-11.2%	355
H-70	295.6	4.7	1.6%	-18.6%	-18.2%	363

An altitude study was performed with spiked whole blood samples at low (30-50 mg/dL), medium (80-120 mg/dL), and high concentrations (240-360 mg/dL) and

control solutions at medium and high concentrations at 0, 1000, 2000, and 3275 meters above sea level. The data submitted support use of the device up to the claimed altitude of 10,000 feet (3048 meters). The results are summarized below.

Low Level Glucose

Bias vs REF										
DUT			DUT 1				DUT 2			
Donor			0 m	1000 m	2000 m	3275m	0 m	1000 m	2000 m	3275m
1	F01	Mean	35.3	39.7	38.0	35.7	36.3	38.7	37.3	37.3
		Bias $_{vs\ REF}$	-5.8%	-1.3%	-4.0%	-7.1%	-3.1%	-3.8%	-5.7%	-2.8%
2	M01	Mean	41.0	40.7	43.0	38.0	39.7	41.3	41.3	38.0
		Bias $_{vs\ REF}$	-3.8%	2.2%	-2.7%	1.1%	-6.9%	3.9%	-6.5%	1.1%
3	F02	Mean	43.7	45.3	40.7	41.3	40.7	43.0	44.0	42.0
		Bias $_{vs\ REF}$	2.0%	-0.8%	-5.6%	1.8%	-5.0%	-5.9%	2.1%	3.4%
4	F03	Mean	36.7	38.7	37.0	41.0	38.3	39.3	38.3	39.3
		Bias $_{vs\ REF}$	-2.5%	-6.4%	-6.3%	1.0%	2.0%	-4.8%	-3.0%	-3.1%
5	M02	Mean	43.0	42.3	42.7	44.7	44.7	43.3	41.7	46.0
		Bias $_{vs\ REF}$	-2.1%	-1.1%	2.6%	-1.2%	1.7%	1.2%	0.2%	1.8%

Mid-Level Glucose

Bias vs REF										
DUT			DUT 1				DUT 2			
Donor			0 m	1000 m	2000 m	3275m	0 m	1000 m	2000 m	3275m
1	F01	Mean	92.3	87.0	94.7	91.3	91.7	87.3	94.0	92.7
		Bias $_{vs\ REF}$	-3.4%	-2.5%	0.5%	1.4%	-4.1%	-2.1%	-0.2%	2.8%
2	M01	Mean	89.3	88.0	95.7	91.0	91.0	89.7	95.0	93.7
		Bias $_{vs\ REF}$	0.8%	-2.9%	-3.1%	-1.9%	2.7%	-1.0%	-3.7%	0.9%
3	F02	Mean	92.0	90.0	95.0	91.7	92.3	88.3	97.0	93.0
		Bias $_{vs\ REF}$	-1.9%	-4.2%	-2.4%	0.4%	-1.6%	-5.9%	-0.3%	1.9%
4	F03	Mean	90.0	88.7	96.3	91.3	87.3	90.0	90.0	93.0
		Bias $_{vs\ REF}$	-0.6%	-0.6%	1.1%	-4.3%	-3.5%	0.9%	-5.6%	-2.5%
5	M02	Mean	89.0	86.7	94.7	92.0	90.3	89.7	95.3	94.0
		Bias $_{vs\ REF}$	0.5%	-1.3%	-1.8%	-1.7%	2.0%	2.1%	-1.1%	0.4%

High Level Glucose

Bias vs REF										
DUT			DUT 1				DUT 2			
Donor			0 m	1000 m	2000 m	3275m	0 m	1000 m	2000 m	3275m
1	F01	Mean	314.0	303.7	325.0	318.3	318.0	308.0	327.7	322.7
		Bias $_{vs\ REF}$	-2.8%	-1.7%	1.2%	-0.5%	-1.5%	-0.3%	2.1%	0.8%
2	M01	Mean	307.7	302.3	317.7	327.7	313.0	310.7	317.0	317.3
		Bias $_{vs\ REF}$	-0.8%	-1.2%	1.5%	-0.7%	1.0%	1.5%	1.3%	-3.8%
3	F02	Mean	321.3	306.3	313.3	329.3	305.7	311.0	325.3	321.0
		Bias $_{vs\ REF}$	1.4%	-2.8%	-3.9%	-2.0%	-3.6%	-1.3%	-0.2%	-4.5%
4	F03	Mean	308.7	315.7	326.3	315.3	314.7	309.7	324.7	325.0
		Bias $_{vs\ REF}$	0.9%	-1.7%	-1.1%	-1.5%	2.8%	-3.5%	-1.6%	1.6%
5	M02	Mean	318.3	306.7	318.7	316.0	309.0	307.7	326.0	318.7
		Bias $_{vs\ REF}$	-2.1%	1.5%	-2.2%	1.9%	-4.9%	1.9%	0.0%	2.8%

f. Assay cut-off:
Not applicable

2. Comparison studies:

a. Method comparison with predicate device:
A consumer study was performed with 139 lay-users and a technician to see if glucose readings from the forearm, palm and fingertip were comparable to a laboratory glucose reference method. Each participant performed their own fingerstick and tested their blood using the instructions in the User's Guide. These clinical samples ranged from 29 – 482 mg/dL. Linear regression analysis of the data yielded the results below:

	Fingerstick vs. Reference Method	Palmstick vs. Ref. Method	Palmstick vs. Fingerstick	Armstick Ref. Method	Armstick vs. Fingerstick
N	139	139	139	139	139
Regression	y = 0.99x – 1.36	y = 0.98x + 2.57	y = 0.98x + 5.05	y = 0.97x – 3.93	y = 0.96x + 0.47
r value	0.989	0.990	0.994	0.990	0.982
Samples < 75 mg/dL within ±15 mg/dL	26/26 (100%)	26/26 (100%)	25/26 (96%)	26/26 (100%)	25/26 (96%)
Samples ≥ 75 mg/dL	110/113 (97%)	110/113 (97%)	110/113 (97%)	108/113 (96%)	105/113 (93%)

within ± 20%					
Total	136/139 (98%)	136/139 (98%)	135/139 (97%)	134/139 (96%)	130/139 (94%)

b. Matrix comparison:
This system is cleared for use with fingerstick, palm, and forearm capillary whole blood 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):
   The sponsor provided a readability study that indicated that the user manual, strip labeling, and control solutions are at an 8th grade reading level.

4. Clinical cut-off:
   Not applicable.

5. Expected values/Reference range:
   The normal fasting adult glucose range for a non-diabetic listed by the sponsor is 70 – 99 mg/dL. Referenced from Diabetes Information - American Association for Clinical Chemistry (AACC)（Electronic Version）.

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 _____
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 provides a single level of glucose control solution with this device. A second level of control solution is available for purchase but is not included in the kit.
   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.