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

A. 510(k) Number:

k120423

B. Purpose for Submission:

Clearance of new device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative Amperometric assay (FAD-Glucose Dehydrogenase)

E. Applicant:

Bionime Corporation

F. Proprietary and Established Names:

Bionime Rightest™ Blood Glucose Monitoring System, Model GM650

GE Talking Blood Glucose Monitoring System, Model GE300

G. Regulatory Information:

1. Regulation section:
   21 CFR: 862.1345, Blood Glucose Test System
   21 CFR 862.1660, Quality control material (assayed and unassayed)

2. Classification:
   Class II
   Class I, reserved

3. Product code:
   NBW – System, Test, Blood Glucose, Over the Counter
   LFR- Glucose Dehydrogenase
   JJX - Quality Control Material (Assayed and Unassayed)

4. Panel:

   75 (clinical chemistry)

H. Intended Use:

1. Intended use(s):
   Same as indications for use

2. Indication(s) for use:

   Bionime Rightest™ Blood Glucose Monitoring System, Model GM650

   The Rightest Blood Glucose Monitoring System GM650 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole samples drawn from the fingertips, palm and forearm. The Rightest Blood Glucose Monitoring System GM650 is intended to be used by a single person and should not be shared.

   The Rightest Blood Glucose Monitoring System GM650 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. The Rightest Blood Glucose Monitoring System GM650 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).

   The Rightest Blood Glucose Test Strip GS650 is for use with the Rightest Blood Glucose meter GM650 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm or forearm.

   The Rightest Control Solution GC650 is for use with the Rightest Blood Glucose meter GM650 and Rightest Blood Glucose Test Strips GS650 to check that the meters and test strip are working together properly and that the test is performing correctly.

   GE Talking Blood Glucose Monitoring System, Model GE300

   The GE Talking Blood Glucose Monitoring System Model GE300 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole samples drawn from the fingertips, palm and forearm. The GE Talking Blood Glucose Monitoring System Model GE300 is intended to be used by a single person and should not be shared.

   The GE Talking Blood Glucose Monitoring System Model GE300 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. The GE Talking Blood Glucose Monitoring System Model GE300 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).

The GE300 Blood Glucose Test Strip is for use with the GE talking blood glucose monitoring system Model GE300 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm or forearm.

The GE300 Control Solution Set is for use with the GE talking blood glucose monitoring system Model GE300 and GE300 Blood Glucose Test Strips to check that the meters and test strip are working together properly and that the test is performing correctly.

3. Special conditions for use statement(s):

- For over-the-counter use
- Not for neonatal use
- Not for screening or diagnosis of diabetes mellitus
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients
- For single-patient use only
- Alternative site testing (AST) testing should only be done during steady-state times (when glucose is not changing rapidly).
- AST should not be used to calibrate continuous glucose monitors (CGMs).
- AST should not be used for insulin dose calculations.
- The GM650 and GE300 BGMS are NOT intended for use by visually impaired patients, therefore, the kit boxes and labeling indicate "Only limited audible information is available".

4. Special instrument requirements:
Rightest GM650 Blood Glucose Meter
GE Talking Blood Glucose Meter, Model GE300

I. Device Description:

The Rightest Blood Glucose Monitoring System Model GM650 consists of a the Rightest GM650 Blood Glucose meter, the Rightest Blood Glucose Test Strips GS650, three levels of Control Solutions, Rightest GD500 Lancing Device for single patient use only and lancets, clear cap (sold separately), carry case, and User Manual.

Each test strip contains the following reagent compositions: flavin adenine dinucleotide-glucose dehydrogenase (9.0% FAD-GDH from Aspergillus Oryzae); potassium ferricyanide (53.7%); and other non-reactive ingredients.

Each box of control solutions contains one vial (4.0 mL) of each aqueous control solution, each: Level 1 (40-50 mg/dL), Level 2 (120 to 150 mg/dL), Level 4 (330 to 360 mg/dL).

GE300 Talking BGMS and Rightest BGMS GM650 meters are identical to each other in every way and share the following components tabulated below:

Rightest Name	Code	GE Name and code
Meter	GM650	GE300 Talking Blood Glucose Meter
Test Strip (10 or 25 strips)	GS650	GE300 Talking Blood Glucose Test Strip (10 or 25 strips)
Control Solution Set (Level 1, Level 2, and Level 4)	GC650	GE300 Talking Blood Glucose Control Solution Set (Level 1, Level 2, and Level 4 Levels)
Lancing Device	GD500	GE Lancing Device
Lancets	GL300	Lancets

The control solutions: L1, L2, L3, L4 and L5 were cleared under k110737 on March 29, 2012. Low (L1), Normal (L2) and High (L4) levels are included in this submission which have been renamed as Level 1, Level 2 and Level 4. The indications for use and labeling are modified accordingly.

The test strips to be used with GM650 and GE300 meters are the same as the GM 700 strips that have been cleared under k110737.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Rightest Blood Glucose Monitoring System Model GM550
   Rightest Control Solutions GC550

2 Predicate 510(k) number(s):

   k092052 and k110737

2. Comparison with predicate:

Similarities and Differences of the Blood Glucose System		
Item	Predicate Device Rightest Blood Glucose Monitoring System, Model GM550 (k092052)	Candidate Device Rightest Blood Glucose Monitoring System GM650 and GE Talking Blood Glucose Monitoring System, Model GE300
Intended Use/Indications for Use	It is intended to be used for quantitative measurement of glucose in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same

Setting	At home and in a clinical settings	Only for single patient use at home
Detection method	Amperometry	Same
Enzyme	Glucose Oxidase	FAD-Glucose Dehydrogenase
Calibration Coding	Auto code	Same
Memory	500 control and glucose (1, 7, 14, 30, 90 day average)	Same
Test range	20 - 600 mg/dL	Same
Hematocrit range	30 - 60%	30-55%
Sample type	Capillary whole blood	Same
Sample sites	Fingertip, forearm, palm	Same
Sample volume	0.75 µL	1 µL
Voice function	No	Yes

Similarities and Differences of the control solution

Predicate Device Rightest Control Solutions GC550 (k110737)	Candidate Device Rightest Control Solutions GC650
To check that the glucose meter and test strips are working together properly	Same
Viscosity-adjusted, aqueous liquid	Same
5 levels	3 levels L1, L2 and L4

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

- ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
- ISO 14971:2007, Medical devices – Application of risk management to medical devices.
- CLSI EP7-A2, Interference Testing in Clinical Chemistry; Approved Guideline.
- IEC 60601-1-2, Medical electrical equipment Part 1-2: General Requirements for Safety-Collateral Standard: Electromagnetic Compatibility- Requirements and tests.
- IEC 60601-1, Medical Electrical Equipment-Part 1: General Requirements for Safety.
- IEC 61000-4-2 Electromagnetic compatibility (EMC)-Part 4-2: Testing and measurement techniques-Electrostatic discharge immunity test.: 2008
- IEC 61000-4-3: Electromagnetic compatibility (EMC) – Part 4-3 2006+A1:2007: Testing and measurement techniques-Radiated, radio-frequency, electromagnetic field immunity test.
- IEC 61000-4-8, Electromagnetic compatibility (EMC)-Part 4-8: Testing and measurement techniques-Power frequency magnetic field immunity test.

L. Test Principle:

The Rightest Blood Glucose Monitoring System, Model GM650 uses electrochemical methodologies. The system quantitatively measures blood glucose levels using an amperometric method. The system employs flavin adenine dinucleotide-glucose dehydrogenase (GDH-FAD) enzyme chemistry. The electrons generated during this reaction are transferred from the blood to the electrodes. The magnitude of the resultant current is proportional to the concentration of glucose in the specimen and the signal is converted into a readout displayed on the meter.

M. Performance Characteristics (if/when applicable):

The Blood Glucose Monitoring Systems - GE300 Talking BGMS and Rightest BGMS GM650 meters are identical to each other except for the trade names. Therefore performance characteristics for only Rightest Blood Glucose Monitoring System GM650 have been provided.

1. Analytical performance:

a. Precision/Reproducibility:

The sponsor performed precision studies in accordance with the ISO 15197 and CLSI EP-5A. Venous whole blood was adjusted to 5 glucose levels 30-50mg/dL, 51-110mg/dL, 111-150mg/dL, 151-250mg/dL, 251-400mg/dL) were used for within-day precision studies. Each glucose level was analyzed in replicates of 10, with 3 test strip lots and 10 meters, for a total of 300 tests per glucose level. Results are summarized below:

Strip Lot No.:Y1650JL01A

Sample		P-01	P-02	P-03	P-04	P-05
N		100	100	100	100	100
Mean	mg/dL	47.0	77.9	139.4	221.6	352.7
SD	mg/dL	1.7	1.5	3.0	4.4	7.7
CV	**%**	3.7%	1.9%	2.2%	2.0%	2.2%

Strip Lot No.:Y1650JK22A

Sample		P-01	P-02	P-03	P-04	P-05
N		100	100	100	100	100
Mean	mg/dL	46.7	78.2	140.3	219.8	349.8
SD	mg/dL	1.6	1.6	2.5	3.9	6.5
CV	**%**	3.5%	2.1%	1.8%	1.8%	1.9%

Strip Lot No.:Y1650JK23A

Sample		P-01	P-02	P-03	P-04	P-05
N		100	100	100	100	100
Mean	mg/dL	46.8	78.0	139.2	222.8	352.7
SD	mg/dL	1.5	1.6	2.8	4.2	8.6
CV	**%**	3.2%	2.0%	2.0%	1.9%	2.4%

In addition to the study above, the sponsor also evaluated day-to-day precision using three levels of glucose control solution samples (32-48 mg/dL, 102-138 mg/dL, 317-429 mg/dL). Three lots of test strips and 10 meters were used in the study, with 1 test performed on each meter per day for 10 days, with 3 test strip lots, and 10 meters for a total of 300 tests per glucose level. Results are summarized below:

Y1650JL01A

Sample		CS-L	CS-N	CS-H
N		100	100	100
Mean	mg/dL	47.42	127.91	375.58
SD	mg/dL	1.4	4.6	9.7
CV	%	2.9%	3.6%	2.6%

Y1650JK22A

Sample		CS-L	CS-N	CS-H
N		100	100	100
Mean	mg/dL	48.05	126.07	376.84
SD	mg/dL	1.6	5.9	10.6
CV	%	3.4%	4.7%	2.8%

Y1650JK23A

Sample		CS-L	CS-N	CS-H
N		100	100	100
Mean	mg/dL	47.42	127.73	375.39
SD	mg/dL	1.4	4.8	10.3
CV	%	3.0%	3.8%	2.7%

b. Linearity/assay reportable range:

Linearity was evaluated using three test strip lots and 15 mixed pools of venous blood samples in glucose concentrations (as measured by YSI) of 0, 9, 29, 50, 86,154, 210, 238, 325, 346, 401, 462, 492, 591, and 629 mg/dL. Each level was measured in triplicate with each of 3 test strip lots and the values from the Rightest GM650 meter were compared with those obtained from YSI-2300. Results from regression analysis:
Test strip lot #1: $y = 1.0025x - 0.0664$; $R^2 = 0.9956$
Test strip lot #2: $y = 1.0226x - 5.0090$; $R^2 = 0.9963$
Test strip lot #3: $y = 1.0009x + 1.8628$; $R^2 = 0.9952$

The results of the study support the sponsor's claimed glucose measurement range of 20-600 mg/dL.

The measuring range of these systems is 20-600 mg/dL. Results equal to or below 20 mg/dL are reported as "Lo" and results greater than or equal to 600 mg/dL reported as "Hi."

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

Control solutions and test strips cleared under k110737.

Traceability:
The Bionime Rightest Model GM650 Blood Glucose Monitoring System is traceable to the NIST SRM 917A reference material.

d. Detection limit:

The measuring range of the system is 20-600 mg/dL. This range was verified by the linearity study (M.1.b).

e. Analytical specificity:
Interference studies were performed by spiking venous blood with two levels of glucose concentrations (60 - 100 and 150 - 300 mg/dL). Each of these samples was divided into a test pool and a control pool and each of 18 potential endogenous and exogenous interfering substances was added to the test pool. Each compound was tested at two concentrations, normal/therapeutic and high/toxic concentrations.

Each sample was analyzed 5 times with the Rightest GM650 meter and the % difference between the interferent containing sample and the control sample calculated. The sponsor defines no significant interference as ≤10% difference relative to the control sample. Results are presented in the table below:

Potential Interfering Substance	Concentration with no Significant Interference (mg/dL)		Potential Interfering Substance	Concentration with no Significant Interference (mg/dL)
Acetaminophen	20		Salicylic Acid	20
Ascorbic Acid	6		Tetracycline	1.5
Bilirubin	40		Tolbutamide	100
Cholesterol	500		Triglycerides	1700
Creatinine	10		Uric Acid	10
Dopamine	2.5		Maltose	200
Ibuprofen	50		Galactose	50
L-Dopa	3.0		Lactose	50
Methyldopa	1.5		Xylose	10

The sponsor has the following limitations in their labeling: Xylose concentrations ≥10 mg/dL and Uric acid ≥10mg/dL may interfere with the test resulting in inaccurate test results.

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor states that this study was performed in accordance with ISO 15197.

Testing was completed by comparing the Rightest Blood Glucose Monitoring System against the YSI-2300 glucose analyzer (reference method). The study was conducted with a total 118 subjects. Three lots of test strips were used in the study.
Fresh venous blood samples and capillary blood from fingertip, palm and forearm (ranging between 30-528 mg/dL glucose concentrations) from different individuals were used, except for five samples with glucose concentrations <50mg/dL that were incubated to allow glucose to glycolize. For concentrations > 400 mg/dL, four spiked samples were used. Samples collected from fingertip, palm and forearm were tested with the Rightest GM 650 and within 5 minutes was also tested with the YSI meter.

Accuracy for first Rightest GM650 measurement results vs. YSI results are summarized below:

For blood glucose concentration < 75 mg/dL

Rightest GM650	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Fingertip	13/15(86.7%)	15/15(100.0%)	15/15(100.0%)
Palm	12/15(80.0%)	15/15(100.0%)	15/15(100.0%)
Forearm	11/15(73.3%)	15/15(100.0%)	15/15(100.0%)

For blood glucose concentration ≧ 75 mg/dL

Rightest GM650	Within ± 5 %	Within ± 10 %	Within ±15 %	Within ± 20%
Fingertip	67/103(65.0%)	92/103(89.3%)	101/103(98.1%)	103/103(100.0%)
Palm	56/103(54.4%)	88/103(85.4%)	102/103(99.0%)	103/103(100.0%)
Forearm	46/103(44.7%)	75/103(72.8%)	100/103(97.1%)	102/103(99.0%)

Results met the criteria from ISO 15197 that states: 95% of the individual glucose results shall fall within±15mg/dL when glucose concentration less than 75mg/dL and within ±20% when glucose concentration ≥75 mg/dL.

Linear Regression analysis

Comparison vs. YSI	Test strip lot	Range of values (mg/dL)	slope	intercept	R
Finger	1	29-533	0.998	-2.83	0.996
	2	30-524	1.000	0.13	0.996
	3	31-529	0.981	2.21	0.997
Palm	1	30-530	1.006	-2.33	0.995
	2	29-530	0.995	2.44	0.996
	3	30-533	0.994	3.34	0.994
Forearm	1	31-533	0.998	-5.08	0.991
	2	29-526	0.989	-1.13	0.994
	3	33-528	0.984	-0.24	0.994

A usability study was conducted as follows:
To assess the performance of the Rightest GM 6500 Blood Glucose Monitoring System in the hands of the intended users, the sponsor performed a study with 161 lay user participants, who collected 161 each of fingerstick and palm samples and 157 forearm samples, at three study locations with three test strip lots. Health care professionals took one further measurement (immediately after) with the Rightest GM650 BGMS, and the results between the lay users and health care professionals

were compared against YSI 2300.

Professional and lay user test results of the fingertip vs YSI

＜75 mg/dL	**Within ± 5 mg/dL**	**Within±10 mg/dL**	**Within±15 mg/dL**	**Within±20m g/dL**
Professional	3/3 (100%)	3/3 (100%)	3/3 (100%)	3/3 (100%)
Lay User	2/3 (66.7%)	3/3 (100%)	3/3 (100%)	3/3 (100%)
≧ 75 mg/dL	**Within ±5 %**	**Within ±10 %**	**Within ±15 %**	**Within ±20 %**
Professional	91/158 (57.6%)	142/158 (89.9%)	157/158 (99.4%)	158/158 (100%)
Lay User	82/158 (51.9%)	139/158 (88.0%)	155/158 (98.1%)	158/158 (100%)

Professional and lay user test results of the palm vs YSI

＜75 mg/dL	**Within ± 5 mg/dL**	**Within±10 mg/dL**	**Within±15 mg/dL**	**Within±20m g/dL**
Professional	3/3 (100%)	3/3 (100%)	3/3 (100%)	3/3 (100%)
Lay User	3/3 (100%)	3/3 (100%)	3/3 (100%)	3/3 (100%)
≧ 75 mg/dL	**Within ±5 %**	**Within±10 %**	**Within±15 %**	**Within ±20 %**
Professional	100/158 (63.3%)	145/158 (91.8%)	158/158 (100%)	158/158 (100%)
Lay User	91/158 (57.6%)	146/158 (92.4%)	154/158 (97.5%)	158/158 (100%)

Professional and lay user test results of the forearm vs YSI

＜75 mg/dL	**Within ± 5 mg/dL**	**Within±10 mg/dL**	**Within±15 mg/dL**	**Within±20m g/dL**
Professional	2/3 (66.7%)	3/3 (100%)	3/3 (100%)	3/3 (100%)
Lay User	3/3 (100%)	3/3 (100%)	3/3 (100%)	3/3 (100%)
≧ 75 mg/dL	**Within ±5 %**	**Within±10 %**	**Within±15 %**	**Within ±20 %**
Professional	80/154 (51.9%)	127/154 (82.5%)	150/154 (97.4%)	154/154 (100%)
Lay User	65/154 (42.2%)	120/154 (77.9%)	148/154 (96.1%)	154/154 (100%)

Linear regression analysis for Lay User Vs YSI

	Rightest GM650 fingertip vs YSI	Rightest GM650 palm vs YSI	Rightest GM650 forearm vs YSI
glucose range (mg/dL)	72.2 ~ 371	72.2 ~ 371	72.2 ~ 371

N	161	161	157
Slope	0.98	0.98	0.96
Intercept	0.76	1.51	-0.22
r	0.98	0.98	0.97

b. Matrix comparison:

This system is for use with fingerstick, palm, and forearm capillary samples. The meter's software adjusts the whole-blood glucose reading to a plasma-equivalent reading.

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:

Expected glucose values for people without diabetes:

Status	Range
Fasting	< 100 mg/dL
Two hrs after meal	< 140 mg/dL

American Diabetes Association: Standard of Medical Care in Diabetes 2011, Diabetes Care, vol.34, supplement 1, S11-S61, January 2011.

N. Instrument Name:

Rightest GM650 Blood Glucose Meter
GE Talking Blood Glucose Meter, Model GE300

O. System Descriptions:

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

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?:
Yes _____(or No __X__

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?:
Yes _____or No _X___

2. Software:
FDA 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:
The glucose test is intended to be used with capillary whole blood from the finger, palm, and forearm only. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:
A single calibration code is programmed into the meters at the time of manufacturing and no user input is required for calibration.

6. Quality Control:
Three levels of aqueous glucose control solutions are available with this system. The meter has a function for the user to select the level of control solution they wish to run to prevent control results from being stored in the internal memory as patient results. Recommendations on when to test the control materials are provided in the labeling. The control solution readings are not included in the average of the patient results when the measurements are performed in the "CS measurement mode". An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. **Hematocrit Study:**
   A study to evaluate the effects of hematocrit was conducted on samples with 6 glucose concentrations (20-50, 60-80, 135-165, 180-220, 270-330 and 360-440 mg/dL) at 6 hematocrit levels (20, 25, 30, 40, 50, 60 and 65%). Each glucose level/hematocrit combination was tested in triplicate on 3 meters using 3 lots of test strips. Results of samples at each hematocrit level were compared to samples with the same glucose concentration at normal (45%) hematocrit as well as to the corresponding YSI value. Data provided for the claimed hematocrit range of 30-55% met the sponsor's acceptance criteria of $\pm$ 15%

2. **Altitude Study:**
   A study was conducted to evaluate the effect of altitude on the GM650 BGMS. Test samples were tested on 3 meters in triplicate with 3 different strip vials using venous whole blood from healthy donors. Three glucose concentrations (ranging from 43.5-335mg/dL) at three corresponding altitude levels (3280, 6561 and 9842 feet,) were tested in a controllable temperature /humidity chamber against a 0 meter level as a control. Each venous blood sample was also tested by the YSI 2300 analyzer. The meter readings obtained were compared to the YSI method and the percent bias was determined at each level against the YSI results. The sponsor showed the bias was within ± 10 % for all three altitude levels tested. Based on the data, the sponsor claims that the GM650 can be used up to 9842 feet

3. **Sample volume study:**
   A sample volume study was performed to verify the minimum test strip sample volume requirement and the test strip fill error requirement established for the BGMS. Three lots of test strips were used to test spiked or glycolized venous whole blood at three glucose concentrations (40-60, 80-120 and 300-330 mg/dL). Blood at each of these concentrations was applied to strips at 6 target sample volumes of 0.6, 0.65, 0.75, 0.8, 1.0, and 1.25µL. The sponsor concluded that sample volumes of ≥0.75 µL produced accurate results (the sponsor showed were within 8%), Samples <0.75 µL gave an Er 4 error code . The labeling provides instructions and graphics to assist the user in obtaining and applying an adequate sample volume.

4. **User performance study:**
   As part of the user performance study summarized in section M.2.a above, the participants were asked to complete a questionnaire to evaluate the ease of use of the device and the clarity of the English language labeling. Overall the users indicated that they could successfully perform the test and that the user manual was written clearly.

5. **Readability assessment:**
   The Flesch-Kincaid readability assessment of the product labeling determined that the Owner's Manuals and test strip inserts for both proposed devices were written at the 8th grade level.

6. Temperature and humidity studies:

Temperature and humidity studies were conducted that demonstrated that the devices can be used at temperatures from 6 to 40°C and at a relative humidity of 10 to 90%. The sponsor tested the extreme combinations of temperature and humidity and the results supported the claimed ranges.

7. Electromagnetic Compatibility:

EMC testing was performed/passed and a certificate granted to Bionime Inc. was provided.

8. Infection Control Studies:

The device is intended for single-patient use only. Discide Ultra disinfecting towelettes with EPA registration #10492-4 were validated demonstrating validation using hepatitis B surface antigen testing using materials from the meter and lancing device. The sponsor also demonstrated that there was no change in performance or in the external materials of the meters and lancing device after 550 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate 5 years of meter and lancing device use. 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 Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.