DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 9, 2015

BIONIME COPORATION
C/O FENG-YU LEE
REGULATORY CONSULTANT
29222 RANCHO VIEJO ROAD, SUITE 218
SAN JUN CAPISTRANO CA 92675

Re: K141292
Trade/Device Name: Rightest Blood Glucose Monitoring System GM700,
Rightest Blood Glucose Monitoring System GM650,
GE200 Blood Glucose Monitoring System
GE 300 Talking Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: April 28, 2015
Received: May 1, 2015

Dear Feng-Yu Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
GE200 Blood Glucose Monitoring System

Indications for Use *(Describe)*
The GE200 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The GE200 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The GE200 Blood Glucose Monitoring System 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 GE200 Blood Glucose Monitoring System 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 GE200 Blood Glucose Test Strips are for use with the GE200 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
GE300 Talking Blood Glucose Monitoring System

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

The GE300 Talking Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by diabetic individuals at home as an aid to monitor the effectiveness of diabetes control. Only limited audible information is available, not intended as an aid for the visually impaired. The GE300 Talking Blood Glucose Monitoring System 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 Talking Blood Glucose Test Strips are for use with the GE300 Talking Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

The GE300 Series Control Solution are for use with the GE300 Talking Blood Glucose Meter and the GE300 Talking Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
Rightest Blood Glucose Monitoring System GM650

Indications for Use *(Describe)*
The Rightest Blood Glucose Monitoring System GM650 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. 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 diabetic individuals at home as an aid to monitor the effectiveness of diabetes control. Only limited audible information is available, not intended as an aid for the visually impaired. 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 Strips GS650 are for use with the Rightest Blood Glucose Meter GM650 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

The Rightest Control Solutions GC650 are for use with the Rightest Blood Glucose Meter GM650 and the Rightest Blood Glucose Test Strip GS650 to check that the meter and test strips are working together properly and that the test is performing correctly.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
Rightest Blood Glucose Monitoring System GM700

Indications for Use *(Describe)*
The Rightest Blood Glucose Monitoring System GM700 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The Rightest Blood Glucose Monitoring System GM700 is intended to be used by a single person and should not be shared.

The Rightest Blood Glucose Monitoring System GM700 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 GM700 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 Strips GS700 are for use with the Rightest Blood Glucose Meter GM700 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: k141292

1. Submitter's Identification:

BIONIME CORPORRATION
NO 100, Sec. 2, Daqing St., South Dist.,
40242 Taichung City, Taiwan
Phone Number: 886-4-23692388
FAX Number: 886-4-22617568

c/o IVDD Regulatory Consultant
29222 Rancho Viejo Road, Suite 218
San Juan Capistrano, CA 92675
Contact Person: Feng-Yu Lee
Phone Number: 1-949-218-0929
Fax Number: 1-218-0928

Date Summary Prepared: April 28, 2015

2. **Name of the Device:**
Rightest Blood Glucose Monitoring System GM700
Rightest Blood Glucose Monitoring System GM650
GE200 Blood Glucose Monitoring System
GE300 Talking Blood Glucose Monitoring System

3. **Common or Usual Name: Blood Glucose Monitoring System**

Product Code	Classification	Regulation Section	Panel
NBW; System, Test, Blood Glucose, Over-the-Counter	Class II	21 CFR 862.1345	Clinical Chemistry 75
LFR; Glucose Dehydrogenase, Glucose	Class II	21 CFR 862.1345	Clinical Chemistry 75

4. **Device Description:**

4.1 Bionime Rightest Blood Glucose Monitoring System GM700 consists of the following devices: Rightest Blood Glucose Meter GM700, Rightest Blood Glucose Test Strip GS700, and Rightest Control Solution GC700. The Rightest Blood Glucose Meter GM700, Rightest Blood Glucose Test Strips GS700 are manufactured by BIONIME Corporation. The Rightest Blood Glucose Meter GM700, when used with the Rightest Blood Glucose Test Strips GS700, quantitatively measures glucose in fresh capillary whole blood. The performance of the Rightest Blood Glucose Monitoring System GM700 is verified by the Rightest Control Solution GC700.

4.2 Bionime Rightest Blood Glucose Monitoring System GM650 consists of the following devices: Rightest Blood Glucose Meter GM650, Rightest Blood Glucose Test Strip GS650, and Rightest Control Solution GC650. The Rightest Blood Glucose Meter GM650, Rightest Blood Glucose Test Strips GS650, and Lancing Device are manufactured by BIONIME Corporation. The Rightest Blood Glucose Meter GM650, when used with the Rightest Blood Glucose Test Strips GS650, quantitatively measures glucose in fresh capillary whole blood. The performance of the Rightest Blood Glucose Monitoring System GM650 is verified by the Rightest Control Solution GC650.

4.3 Bionime GE200 Blood Glucose Monitoring System consists of the following devices: GE200 Blood Glucose Meter, GE200 Blood Glucose Test Strip, and GE200 Control Solution. The GE200 Blood Glucose Meter, GE200 Blood Glucose Test Strips are manufactured by BIONIME Corporation. The GE200 Blood Glucose Meter, when used with the GE200 Blood Glucose Test Strips, quantitatively measures glucose in fresh capillary whole blood. The performance of the GE200 Blood Glucose Monitoring System is verified by the GE200 Control Solution.

4.4 Bionime GE300 Talking Blood Glucose Monitoring System consists of the following devices: GE300 Talking Blood Glucose Meter, GE300 Talking Blood Glucose Test Strip, and GE300 Series Control Solution. The GE300 Talking Blood Glucose Meter, GE300 Talking Blood Glucose Test Strips are manufactured by BIONIME Corporation. The GE300 Talking Blood Glucose Meter, when used with the GE300 Talking Blood Glucose Test Strips, quantitatively measures glucose in fresh capillary whole blood. The performance of the GE300 Talking Blood Glucose Monitoring System is verified by the GE300 Series Control Solution.

5. **Intended Use (identical to k123008):**

Rightest BGMS GM700/GM650

5.1

The Rightest Blood Glucose Monitoring System GM700 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The Rightest Blood Glucose Monitoring System GM700 is intended to be used by a single person and should not be shared.

The Rightest Blood Glucose Monitoring System GM700 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 GM700 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 Strips GS700 are for use with the Rightest Blood Glucose Meter GM700 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

5.2

The Rightest Blood Glucose Monitoring System GM650 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. 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 diabetic individuals 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 Strips GS650 are for use with the Rightest Blood Glucose Meter GM650 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

GE GE200/GE300 BGMS

5.3

The GE200 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The GE200 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The GE200 Blood Glucose Monitoring System 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 GE200 Blood Glucose Monitoring System 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 GE200 Blood Glucose Test Strips are for use with the GE200 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

5.4

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

The GE300 Talking Blood Glucose Monitoring System is intended for self -testing outside the body (in vitro diagnostic use) by diabetic individuals at home as an aid to monitor the effectiveness of diabetes control. The GE300 Talking Blood Glucose Monitoring System 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 Talking Blood Glucose Test Strips are for use with the GE300 Talking Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

6. Predicate Device Information:

The Rightest and GE series Blood Glucose Monitoring Systems are substantially equivalent to the predicate devices below:

Name:	Rightest BGMS GM700
Device Company:	Bionime Corporation
510(K) Number:	k110737/k123008

Name:	Rightest BGMS GM650
Device Company:	Bionime Corporation
510(K) Number:	k120423/k123008

Name:	GE200 BGMS
Device Company:	Bionime Corporation
510(K) Number:	k123008

Name:	GE300 BGMS
Device Company:	Bionime Corporation
510(K) Number:	k120423/k123008

7. Comparison to Predicate Devices: Specification Comparison

A. Rightest Blood Glucose Monitoring Systems, GM700, GM650

Item	Subject Device	Predicate Device (k123008)
	Rightest BGMS **GM700** (modified test strip)	Rightest BGMS GM700
Similarities and Differences		
Intended 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
Detection Method	Dehydrogenase Electrochemical Biosensor	same
Measuring Time	5 sec	same
Measurement Unit	mg/dL	same
Sample Site	Capillary whole blood from fingertips, forearm or palm	same
Voice Function	No	same
Meter Dimensions	99 mm x 46 mm x 17.5 mm	same
Meter Weight	57 ± 5 g with battery	same
Power Supply	One CR2032 battery	same
Battery Life	Approx. 1000 measurements	same
Backlight	No	same
Interface	LCD display	same
LCD Display Area	52.6 mm x 32.0 mm	same
Memory Capacity	500 blood glucose test results	same
Interference	Uric acid ≧ 16 mg/dL Xylose ≧ 18 mg/dL Ascorbic acid ≧ 3 mg/dL Dopamine HCl ≧ 1.25 mg/dL L-Dopa ≧ 2 mg/dL	Uric acid ≧ 16 mg/dL Xylose ≧10 mg/dL Ascorbic acid ≧3 mg/dL Dopamine HCl ≧ 1.25 mg/dL L-Dopa ≧ 2 mg/dL
Coding	Auto Coding	same
Operating Temperature Range	43-111°F (6-44°C)	same
Operating Relative Humidity Range	10-90%	same
Test Strip Storage Conditions	39-86 °F (4-30°C), 10-90% relative humidity	same

Test Strip Shelf Life (after opened vial)	4 months	same
Meter Storage Conditions	14-140 °F (-10-60°C)	same
Control Solution	3 levels (Level 1, 2, and 4)	same
Strip Reagent Enzyme	FAD-Glucose Dehydrogenase	same
Hematocrit Range	20-65%	30-55%
Sample Volume	0.75 µL	same
Measurement Range	20-600 mg/dL	same

Item	Subject Device	Predicate Device **(k123008)**
	Rightest BGMS **GM650** (modified test strip)	Rightest BGMS GM650
Similarities and Differences		
Intended 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
Detection Method	Dehydrogenase Electrochemical Biosensor	same
Measuring Time	5 sec	same
Measurement Unit	mg/dL	same
Sample Site	Capillary whole blood from fingertips, forearm or palm	same
Voice Function	Yes	same
Meter Dimensions	105 mm x 50 mm x 18 mm	same
Meter Weight	80.0 ± 5 g with batteries	same
Power Supply	Two 1.5V(AAA) batteries	same
Battery Life	Approx. 1000 measurements	same
Backlight	No	same
Interface	LCD display	same
LCD Display Area	48mm x 34mm	same
Memory Capacity	500 blood glucose test results	same
Interference	Uric acid ≧ 16 mg/dL Xylose ≧18 mg/dL Ascorbic acid ≧3 mg/dL Dopamine HCl ≧ 1.25 mg/dL L-Dopa ≧ 2 mg/dL	Uric acid ≧ 16 mg/dL Xylose ≧10 mg/dL Ascorbic acid ≧3 mg/dL Dopamine HCl ≧ 1.25 mg/dL L-Dopa ≧ 2 mg/dL

Coding	Auto Coding	same
Operating Temperature Range	43-111°F (6-44C)	same
Operating Relative Humidity Range	10-90%	same
Test Strip Storage Conditions	39-86 °F (4-30°C), 10-90% relative humidity	same
Test Strip Shelf Life (after opened vial)	4 months	same
Meter Storage Conditions	14-140 °F (-10-60°C)	same
Control Solution	3 levels (Level 1, 2, and 4)	same
Strip Reagent Enzyme	FAD-Glucose Dehydrogenase	same
Hematocrit Range	20-65%	30-55%
Sample Volume	0.75 μL	same
Measurement Range	20-600 mg/dL	same

B. GE Blood Glucose Monitoring Systems, GE200, GE300

Item	Subject Device	Predicate Device **(k123008)**
	GE200 BGMS (modified test strip)	GE BGMS GE200
Similarities and Differences		
Intended 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
Detection Method	Dehydrogenase Electrochemical Biosensor	same
Measuring Time	5 sec	same
Measurement Unit	mg/dL	same
Sample Site	Capillary whole blood from fingertips, forearm or palm	same
Memory Capacity	1000 blood glucose test results	same
Voice Function	No	same
Meter Dimensions	96 mm x 46 mm x 17.5 mm	same
Meter Weight	65 ± 5 g with batteries	same
Power Supply	Two CR2032 batteries	same

Battery Life	Approx. 1000 measurements	same
Backlight	Yes	same
Interface	LCD display	same
LCD Display Area	55mm x 37mm	same
Interference	Uric acid ≧ 16 mg/dL Xylose ≧18 mg/dL Ascorbic acid ≧ 3 mg/dL Dopamine HCl ≧ 1.25 mg/dL L-Dopa ≧ 2 mg/dL	Uric acid ≧ 16 mg/dL Xylose ≧10 mg/dL Ascorbic acid ≧3 mg/dL Dopamine HCl ≧ 1.25 mg/dL L-Dopa ≧ 2 mg/dL
Coding	Auto Coding	same
Operating Temperature Range	43-111°F (6-44C)	same
Operating Relative Humidity Range	10-90%	same
Test Strip Storage Conditions	39-86 °F (4-30°C), 10-90% relative humidity	same
Test Strip Shelf Life (after opened vial)	4 months	same
Meter Storage Conditions	14-140 °F (-10-60°C)	same
Control Solution	3 levels (Level 1, 2, and 4)	same
Strip Reagent Enzyme	FAD-Glucose Dehydrogenase	same
Hematocrit Range	20-65%	30-55%
Sample Volume	0.75 µL	same
Measurement Range	20-600 mg/dL	same

Item	Subject Device	Predicate Device **(k123008)**
	GE300 BGMS (modified test strip)	GE BGMS GE300
Similarities and Differences		
Intended 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
Detection Method	Dehydrogenase Electrochemical Biosensor	same
Measuring Time	5 sec	same
Measurement Unit	mg/dL	same

Sample Site	Capillary whole blood from fingertips, forearm or palm	same
Voice Function	Yes	same
Meter Dimensions	105 mm x 50 mm x 18 mm	same
Meter Weight	80.0 ± 5 g with batteries	same
Power Supply	Two 1.5V(AAA) batteries	same
Battery Life	Approx. 1000 measurements	same
Backlight	No	same
Interface	LCD display	same
LCD Display Area	48mm x 34mm	same
Memory Capacity	500 blood glucose test results	same
Interference	Uric acid ≧ 16 mg/dL Xylose ≧ 18 mg/dL Ascorbic acid ≧ 3 mg/dL Dopamine HCl ≧ 1.25 mg/dL L-Dopa ≧ 2 mg/dL	Uric acid ≧ 16 mg/dL Xylose ≧10 mg/dL Ascorbic acid ≧3 mg/dL Dopamine HCl ≧ 1.25 mg/dL L-Dopa ≧ 2 mg/dL
Coding	Auto Coding	same
Operating Temperature Range	43-111°F (6-44C)	same
Operating Relative Humidity Range	10-90%	same
Test Strip Storage Conditions	39-86 °F (4-30°C), 10-90% relative humidity	same
Test Strip Shelf Life (after opened vial)	4 months	same
Meter Storage Conditions	14-140 °F (-10-60°C)	same
Control Solution	3 levels (Level 1, 2, and 4)	same
Strip Reagent Enzyme	FAD-Glucose Dehydrogenase	same
Hematocrit Range	20-65%	30-55%
Sample Volume	0.75 µL	same
Measurement Range	20-600 mg/dL	same

8. <u>Technology Characteristics:</u>

Bromine's Rightest™ GM700/GM650 and GE200/GE300 GDH Strip with revised HCT range, is paired with electronic device that utilizes the electrical characteristic technology for measuring the glucose level in human blood. A relatively small drop of blood is placed on a disposable test strip coated with FAD-glucose Dehydrogenase (FAD-GDH) which interacts with the software driven digital talking meter. Within five seconds, the level of blood glucose will be shown on the digital display screen.

Rightest™ GM700/GM650 and GE200/GE300 GDH BGMS Test Strip, with revised HCT range, requires only minimum of 0.75 microliter of blood for the testing, therefore it reduces the time and effort required for testing and improves the compliance of diabetic people to their testing regimens.

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Three meter models were used for testing: GM650/GE300, GM700, and GE200. GDH (GS700/GS650/GS750) test strip was used for testing. GS700, GS650, and GS750 test strips are identical to each other for Rightest brand, GE200 and GE300 test strips are identical to GS750 and GS650 with the exception of trade name.

Non-clinical tests were evaluated to establish the performance, functionality, safety and reliability of the Rightest™ GM700/GM650 and GE200/GE300 GDH Strip with revised HCT range. The performed evaluations include:
Linearity and sensitivity, readability assessment, safety test, precision, specimen volume, interference, hematocrit, and test strip stability (close vial and open vial), are summarized below:

Linearity
To reevaluate linearity of HCT revised test strip, 3 lots of revised blood glucose test strips (GS650/GS700/GS750, HCT 20-65%) were used to evaluate detection range. Venous blood samples spiked to 14 levels of glucose concentrations were used, ranging from low to high level (0 to 640 mg/dL), and evaluated compared to reference method YSI 2300.

The tested glucose concentration ranged from 0 to 640 mg/dL and hematocrit value from 20-65%. Analysis of results indicated linear regression between device and reference method shows mean slopes above 1.00 and R^2 values above 0.99. The results support the claim that glucose assay is linear from 20-600 mg/dL – identical to prior 510k cleared claims.

Precision:
Based on the requirements and standards of ISO 1597:2003 to reevaluate the precision of the Rightest and GE series Blood Glucose Monitoring Systems (GM700/GM650/GE200/GE300), the precision study evaluates repeatability of between-day testing, conducted over 10 days at 5 glucose concentrations. 10 meters (3 models) were evaluated for repeatability as well as intermediate precision. 3 lots of revised test strips (GS650/GS700/GS750, HCT range 20-65%) were used; 500 test strips were used for within-day and 300 test strips were used for between-day testing. The venous blood sample results were compared against reference method YSI 2300 Analyzer.

The repeatability evaluation and intermediate precision evaluation results of Rightest and GE series Blood Glucose Monitoring Systems (GM700/GM650/GE200/GE300) demonstrate that repeatability of within-day is evaluated at 5 glucose concentrations and falls within the acceptance criteria.

Specimen Volume

The Specimen Volume Study reevaluated the specimen volume of Rightest and GE series Blood Glucose Monitoring Systems (GM700/GM650/GE200/GE300), using 3 lots of revised test strips (GS650/GS700/GS750, HCT range 20-65%), testing venous blood at 3 glucose concentration levels and at 9 specimen volumes ranging from 0.60 to 3.0 μL. The obtained study results support the existing claimed minimum blood specimen volumes of 0.75μL, which is unaffected with the recent design change.

Interference Study

The Interference Study was performed under CLSI: EP7-A2, using 2 glucose levels of venous blood samples and 19 interference substances to reevaluate the interference the Rightest and GE series Blood Glucose Monitoring Systems (GM700/GM650/GE200/GE300). 3 lots of revised test strips (GS650/GS700/GS750, HCT range 20-65%) were used.

According to study results, xylose (20 and 40 mg/dL), ascorbic acid (6 mg/dL), dopamine (2.5 mg/dL), and uric acid (20 and 24 mg/dL) indicate percentage of interference over ±10% bias in normal glucose concentration, and xylose (40 mg/dL) over ±10% bias in high glucose concentration. This may lead to inaccurate test results, and is stated in the limitations section of the test strip package insert. The remaining 15 interference substances are within the criteria for the 2 glucose concentrations.

Altitude

The Altitude Effect Study was designed to evaluate the performance of Rightest and GE series Blood Glucose Monitoring Systems (GM700/GM650/GE200/GE300) under environment factors at 3 different altitudes: 0, 1000, 2000 and 3000 meters (0, 3280, 6561, and 9842 ft.) above sea level. Test procedures were performed in 3 replicates using 3 lots of revised test strips (GS650/ GS700/GS750, HCT range 20-65%) with glucose control solutions at 3 levels – low, normal and high concentration. The results were compared against reference method YSI 2300 Analyzer.

The obtained study results indicate that the stability of bias compared to the REF during various operated altitude were all within the criteria.

Operation Temperature and Humidity Study

The Operating Temperature and Humidity Study was designed to evaluate the performance of revised GDH test strip under environment factors of operated temperature and humidity. 6 various temperature and humidity conditions using three lots of revised test strips (GS650/GS700/GS750, HCT 20-65%) with glucose control solutions at 3 levels – low, normal and high concentration, and each sample was tested in 5 replicates. The results were compared against reference method YSI 2300 Analyzer.

The obtained study results indicate that the stability of bias compared to the REF during various operated temperature and humidity were all within the criteria. The results demonstrated operation conditions at 43-111°F and 10-90% humidity remain unaffected with the HCT specification change.

Hematocrit Study

The Hematocrit Study was designed to evaluate the Hematocrit levels for revised GS650/GS700/GS750 GDH test strip with HCT range from 20-65%, 6 glucose concentration levels of venous blood samples were evaluated. Three lots of revised test strips (GS650/GS700/GS750) were used, and each sample was tested in 5 replicates. The results were compared against reference method YSI 2300 Analyzer.

The obtained study results indicate that the stability compared to the REF during various HCT ranges were all within the criteria. The acceptable HCT range of the revised test strips is 20-65%.

These studies and evaluations were either performed internally by professional personnel in Bionime or by third party, performed by qualified personnel, with proper calibrated/maintained equipment and under properly-controlled environmental conditions. All of the evaluated performances passed and meet the acceptance criteria set in the study protocol.

9. Discussion of Clinical Tests Performed:

Three meter models were used for testing: GM650/GE300, GM700, and GE200. GDH (GS700/GS650/GS750) test strip was used for testing. GS700, GS650, and GS750 test strips are identical to each other for Rightest brand, GE200 and GE300 test strips are identical to GS750 and GS650 with the exception of trade name.

System Accuracy Study (Whole Blood):

The accuracy studies of Rightest™ GS650/GS700/GS750 Strip with revised HCT range with previous FDA cleared Rightest Blood Glucose Monitoring Systems: GM700, GM650/GE200 and GE300 meters, were performed by comparing whole blood (plasma equivalent) glucose values on the Rightest™ GM700/GM650 and GE200/GE300 GDH Strip with revised HCT range with plasma glucose values on reference lab instrument.

A total of 120 patients were participated. The study result demonstrates that the accuracy of Rightest™ GM700/GM650/GE200/GE300 GDH Strip with revised HCT range met the acceptance criteria, there was no significant difference in slope, intercept, and correlation coefficient.

Lay User Study

A Lay User Performance Evaluation Study was performed to demonstrate that lay users could obtain accurate results using the subject devices. The study was performed using capillary whole blood from fingertip, palm and forearm sample sites by evaluating total of 100 laypersons. The study result shows substantial equivalence to predicate device used in finger, palm and forearm position.

10. Conclusions:

Results of performance evaluation of the Rightest™ GM700/GM650 and GE200/GE300 GDH Strip with revised HCT range demonstrates that:

Subject devices Rightest BGMS GM700/GM650 and GE200/GE300 BGMS with revised HCT specification are substantially equivalent to the predicate devices Rightest Blood Glucose Monitoring System GM700/GM650 and GE200/GE300 BGMS (k123008) in commercial distribution.