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

July 6, 2017

Bionime Corporation
% Feng-Yu Lee, Principal Consultant
Dynamic Biotech Inc. dba IVDD Regulatory Consultant
29222 Rancho Viejo Road, Suite 218
San Juan Capistrano, California 92675

Re: K170143
Trade/Device Name: GE Blood Glucose Monitoring System 180, GE Blood Glucose Monitoring System 182, Rightest Blood Glucose Monitoring System GM280, Rightest Blood Glucose Monitoring System GM280B
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: May 30, 2017
Received: June 7, 2017

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 Part 801 and Part 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 regulation (21 CFR Part 801 and Part 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,

Kellie B. Kelm -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 below.

510(k) Number *(if known)*
k170143

Device Name
Rightest Blood glucose monitoring System GM280B

Indications for Use *(Describe)*
The Rightest Blood Glucose Monitoring System GM280B 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 GM280B is intended to be used by a single person and should not be shared.

The Rightest Blood Glucose Monitoring System GM280B 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 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 GS280 is used with Rightest meter GM280B for the quantitative measurement of 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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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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 below.

510(k) Number *(if known)*
k170143

Device Name
GE Blood glucose monitoring System 182

Indications for Use *(Describe)*
The GE Blood Glucose Monitoring System 182 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 GE Blood Glucose Monitoring System 182 is intended to be used by a single person and should not be shared.

The GE Blood Glucose Monitoring System 182 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 Blood Glucose Monitoring System 182 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 GE Blood Glucose Strip 180 is used with GE Blood Glucose Monitoring Meter 182 for the quantitative measurement of 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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Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k170143

Device Name
Rightest Blood glucose monitoring System GM280

Indications for Use *(Describe)*
The Rightest Blood Glucose Monitoring System GM280 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 GM280 is intended to be used by a single person and should not be shared.

The Rightest Blood Glucose Monitoring System GM280 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 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 GS280 is used with Rightest meter GM280 for the quantitative measurement of 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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Indications for Use

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

510(k) Number *(if known)*
k170143

Device Name
GE Blood glucose monitoring System 180

Indications for Use *(Describe)*
The GE Blood Glucose Monitoring System 180 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 GE Blood Glucose Monitoring System 180 is intended to be used by a single person and should not be shared.

The GE Blood Glucose Monitoring System 180 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 Blood Glucose Monitoring System 180 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 GE Blood Glucose Strip 180 is used with GE Blood Glucose Monitoring Meter 180 for the quantitative measurement of 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 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

The assigned 510(k) number is: k170143

1. Submitter's Identification:

BIONIME CORPORATION
NO 100, Sec. 2, Daqing St., South Dist., 40242 Taichung City, Taiwan
Contact Person: Mr. Roy Huang
Phone Number: 886-4-23692388
FAX Number: 886-4-22617568

Date Summary Prepared: July 6, 2017

2. Name of the Device:
Rightest Blood Glucose Monitoring System GM280
Rightest Blood Glucose Monitoring System GM280B
GE Blood Glucose Monitoring System 180
GE Blood Glucose Monitoring System 182

3. Common or Usual Name: Glucose test system

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

4. Device Description:

The Rightest and GE Blood Glucose Monitoring System series consists of the following devices: Blood Glucose Meter, Blood Glucose Test Strip, Control Solution, lancing device and sterile lancets. The Blood Glucose Meter, Blood Glucose Test Strips, and Lancing Device are manufactured by BIONIME Corporation.

The Rightest Blood Glucose Meter GM280 and Rightest Blood Glucose Meter GM280B, when used with the Rightest Blood Glucose Test Strips GS280, quantitatively measure glucose in fresh capillary whole blood. The performance of the Rightest Blood Glucose Monitoring System GM280 and Rightest Blood Glucose Monitoring System GM280B are verified by the Rightest Control Solution GC550.

The GE Blood Glucose Meter 180 and GE Blood Glucose Meter 182, when used with the GE Blood Glucose Test Strips 180, quantitatively measure glucose in fresh capillary whole

blood. The performance of the GE Blood Glucose Monitoring System 180 and GE Blood Glucose Monitoring System 182 are verified by the Rightest Control Solution GC550.

5. Intended Use:

Rightest Blood Glucose Monitoring System GM280

The Rightest Blood Glucose Monitoring System GM280 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 GM280 is intended to be used by a single person and should not be shared.
The Rightest Blood Glucose Monitoring System GM280 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 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 GS280 is used with Rightest meter GM280 for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Rightest Blood Glucose Monitoring System GM280B

The Rightest Blood Glucose Monitoring System GM280B 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 GM280B is intended to be used by a single person and should not be shared.
The Rightest Blood Glucose Monitoring System GM280B 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 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 GS280 is used with Rightest meter GM280B for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

GE Blood Glucose Monitoring System 180

The GE Blood Glucose Monitoring System 180 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 GE Blood Glucose Monitoring System 180 is intended to be used by a single person and should not be shared.
The GE Blood Glucose Monitoring System 180 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 Blood Glucose Monitoring System 180 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 GE Blood Glucose Strip 180 is used with GE Blood Glucose Monitoring Meter 180 for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

GE Blood Glucose Monitoring System 182

The GE Blood Glucose Monitoring System 182 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 GE Blood Glucose Monitoring System 182 is intended to be used by a single person and should not be shared.
The GE Blood Glucose Monitoring System 182 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 Blood Glucose Monitoring System 182 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 GE Blood Glucose Strip 180 is used with GE Blood Glucose Monitoring Meter 182 for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

6. Predicate Device Information:

The Rightest Blood Glucose Monitoring System GM280, Rightest Blood Glucose Monitoring System GM280B, GE Blood Glucose Monitoring System 180 and GE Blood Glucose Monitoring System 182 Blood Glucose Monitoring Systems are substantially equivalent to the following brand of Rightest Blood Glucose Monitoring System:

Name:	GE333 Blood Glucose Monitoring System
Device Company:	Bionime Corporation
510(K) Number:	K143387

7. Comparison to Predicate Devices:

Specification Comparison

Specification	**Subject Devices**		**Predicate Device**
	Rightest GM280	Rightest GM280B	GE333
	GE180	GE182	
Indications for Use	Over-The-Counter: For single-patient use only, in-vitro diagnostic use only by individuals with diabetes at home		
Measurement Technology	Glucose Oxidase Electrochemical Sensor		
Sample Type	Capillary whole blood		
Minimum Sample Volume	0.75 μL		
Primary Site Testing	Fingertip		
Alternative Site Testing	Forearm, Palm		
Unit of Measurement	mg/dL		
Measuring Range	20-600 mg/dL		
Measuring Time	5 seconds		
Hematocrit	20-60 %		
Control Solution	3 levels (Level 1, 2, and 4) Rightest Control Solution GC550		
Maximum Altitude	10745 feet (3275 m)		
Operating Conditions	Temperature 50 ~104 °F (10 ~ 40°C), 10 ~ 90% Relative Humidity		
Meter Storage Conditions	14 ~140 °F (-10 ~ 60°C)		
Test Strip Storage Conditions	39 ~86 °F (4 ~ 30°C), 10-90% relative humidity		
Test Strip Shelf Life (After Opening)	3 months		
Interference	Ascorbic acid > 3 mg/dL Glutathione reduced >60 mg/dL Uric Acid > 12 mg/dL		Ascorbic acid ≧ 5 mg/dL Cholesterol ≧ 600 mg/dL Uric acid ≧ 10 mg/dL

Test Strip Reagent	Glucose Oxidase (GOD) 18.8 % Potassium Ferricyanide 37.7 % Non-reactive Ingredients 43.5 %		Glucose Oxidase (GOD) 14.8% Potassium ferricyanide 39.5% Non-reactive ingredients 45.7%
Wireless module	No	Bluetooth 4.0 (Low energy)	
Memory Capacity	500 blood glucose test results with date and time		
Power Saving	Turn off automatically 2 minutes after last user action / Press the main button for 3 seconds.		
Coding	Auto coding		
Monitor	LCD display		
Backlight	No		
Power Supply	One CR2032 battery		Two AAA batteries
Battery Life	1000 tests		About 800 tests
Meter Dimension	82mm*45mm*15.5mm		90.6mm*46mm*16.5mm
LCD display area	34 mm*27.5mm		39mm*39.5mm
Meter Weight	43.0± 5g with batteries		81.0 ± 5g with batteries
Color	white/gray		white/green

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

Verification and validation of these blood glucose systems evaluated to establish the performance, functionality, and reliability of the Rightest Blood Glucose Monitoring System GM280, Rightest Blood Glucose Monitoring System GM280B, GE Blood Glucose Monitoring System 180, and GE Blood Glucose Monitoring System 182 Blood Glucose Monitoring Systems. The evaluation included precision, linearity, interference, sample volume and hematocrit.

9. Discussion of Clinical Tests Performed:

System Accuracy Study:
The system accuracy study of the Rightest Blood Glucose Monitoring System GM280 was performed by comparing capillary and venous whole blood (plasma equivalent) glucose values on the Rightest Blood Glucose Meter GM280 with glucose values on lab instrument YSI 2300 Plus Glucose Analyzer.

A total of 104 patients participated. The study results demonstrate that the accuracy of Rightest Blood Glucose Monitoring System GM280 met the acceptance criteria.

User Performance Study:

The user performance study was performed to demonstrate that English speaking and reading lay users across all educational backgrounds can easily understand and follow the labeling/user instructions to obtain accurate results while using Rightest Blood Glucose Monitoring System GM280B.

A total of 135 subjects participated. The study results demonstrate that the user accuracy and ease of use (via participant questionnaire scoring) Rightest Blood Glucose Monitoring System GM280B meet the acceptance criteria.

10. Conclusions:

Results of performance evaluation of the Rightest Blood Glucose Monitoring System GM280, Rightest Blood Glucose Monitoring System GM280B, GE Blood Glucose Monitoring System 180, and GE Blood Glucose Monitoring System 182 demonstrate that the devices are substantially equivalent to the predicate device, GE333 Blood Glucose Monitoring System.