August 17, 2018

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

Re: K173638
Trade/Device Name: Rightest Blood Glucose Monitoring System Max
Rightest Blood Glucose Monitoring System Max Plus
GE Blood Glucose Monitoring System Max
GE Blood Glucose Monitoring System Max Plus
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: June 15, 2018
Received: July 20, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k173638

Device Name
Rightest Blood Glucose Monitoring System Max

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

Rightest Blood Glucose Monitoring System Max 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. It 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 Monitoring System Max is comprised of the Rightest Blood Glucose Test Strip Max and the Rightest Meter Max.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k173638

Device Name
Rightest Blood Glucose Monitoring System Max Plus

Indications for Use *(Describe)*
Rightest Blood Glucose Monitoring System Max Plus with Bluetooth function 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. It is intended to be used by a single person and should not be shared.

Rightest Blood Glucose Monitoring System Max Plus with Bluetooth function 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. It 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 Monitoring System Max Plus is comprised of the Rightest Blood Glucose Test Strip Max and the Rightest Meter Max Plus.

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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Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k173638

Device Name
GE Blood Glucose Monitoring System Max

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

GE Blood Glucose Monitoring System Max 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. It 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 Monitoring System Max is comprised of the GE Blood Glucose Test Strip Max and the GE Meter Max.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k173638

Device Name
GE Blood Glucose Monitoring System Max Plus

Indications for Use *(Describe)*
GE Blood Glucose Monitoring System Max Plus with Bluetooth function 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. It is intended to be used by a single person and should not be shared.

GE Blood Glucose Monitoring System Max Plus with Bluetooth function 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. It 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 Monitoring System Max Plus is comprised of the GE Blood Glucose Test Strip Max and the GE Meter Max Plus.

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 SMDA l990 and 21 CFR §807.92.

The assigned 510(k) number is: k173638

1. Submitter's Identification:

BIONIME CORPORRATION
NO 100, Sec. 2, Daqing St., South Dist., 40242 Taichung City, Taiwan
Contact Person: Roy Huang
Phone Number: 886-4-23692388
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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: 1-949-218-0928

Date Summary Prepared: August 15th, 2018

2. Name of the Device:
Rightest Blood Glucose Monitoring System Max
Rightest Blood Glucose Monitoring System Max Plus
GE Blood Glucose Monitoring System Max
GE Blood Glucose Monitoring System Max Plus

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:

For Over-the-Counter Setting:
Rightest Blood Glucose Monitoring System Max and Rightest Blood Glucose Monitoring System Max Plus, consist 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.

Rightest Meter Max and Rightest Meter Max Plus, when used with the Rightest Test Strips Max, quantitatively measure glucose in fresh whole blood samples from capillary. The performance of Rightest Blood Glucose Monitoring System Max and Rightest Blood Glucose Monitoring System Max Plus are verified by the Rightest Control Solution GC700.

GE Blood Glucose Monitoring System Max and GE Blood Glucose Monitoring System Max Plus, consist 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.

GE Meter Max and GE Meter Max Plus, when used with the GE Test Strips Max, quantitatively measure glucose in fresh whole blood samples from capillary. The performance of GE Blood glucose monitoring System Max and GE Blood glucose monitoring System Max Plus are verified by the Rightest Control Solution GC700.

5. Intended Use:

Rightest Blood Glucose Monitoring System Max

Rightest Blood Glucose Monitoring System Max 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. It is intended to be used by a single person and should not be shared.

Rightest Blood Glucose Monitoring System Max 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. It 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 Monitoring System Max is comprised of the Rightest Blood Glucose Test Strip Max and the Rightest Meter Max.

Rightest Blood Glucose Monitoring System Max Plus

Rightest Blood Glucose Monitoring System Max Plus with Bluetooth function 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. It is intended to be used by a single person and should not be shared.

Rightest Blood Glucose Monitoring System Max Plus with Bluetooth function 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. It 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 Monitoring System Max Plus is comprised of the Rightest Blood Glucose Test Strip Max and the Rightest Meter Max Plus.

GE Blood Glucose Monitoring System Max

GE Blood Glucose Monitoring System Max 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. It is intended to be used by a single person and should not be shared.

GE Blood Glucose Monitoring System Max 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. It 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 Monitoring System Max is comprised of the GE Blood Glucose Test Strip Max and the GE Meter Max.

GE Blood Glucose Monitoring System Max Plus

GE Blood Glucose Monitoring System Max Plus with Bluetooth function 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. It is intended to be used by a single person and should not be shared.

GE Blood Glucose Monitoring System Max Plus with Bluetooth function 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. It 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 Monitoring System Max Plus is comprised of the GE Blood Glucose Test Strip Max and the GE Meter Max Plus.

6. Predicate Device Information:

Rightest and GE Blood Glucose Monitoring Systems Max and Max Plus are substantially equivalent to:

Rightest Blood Glucose Monitoring System GM720
Device Company: Bionime Corporation
510(K) Number: K140210

7. Comparison to Predicate Devices:

Models	**Rightest BGMS Max Plus (New Device)**	**Rightest BGMS Max (New Device)**	**Rightest BGMS GM720 (Predicate Device) K140210**
	GE BGMS Max Plus (New Device)	**GE BGMS Max (New Device)**	

Measurement Technology	Dehydrogenase Electrochemical Sensor	
Sample Type	Fresh capillary whole blood	
Alternative Sample Site	The fingertips, palm, forearm.	
minimum sample volume	0.75 microliter	
Test Time	5 seconds	
Control Solution	3 levels (Level 1, 2, and 4) Rightest Control Solution GC700	
Operating Conditions	Temperature 43 ~111 ℉ (6 ~ 44℃), 10 ~ 90％ Relative Humidity	
Meter Storage Conditions	14 ~140 ℉ (-10 ~ 60℃)	
Test Strip Shelf Life (After Opening)	4 months	
Hematocrit Range	10 - 70 %	20 - 65%
Measuring Range	10-600 mg/dL	20-600 mg/dL
Test Strip Reagent	1. FAD-Glucose dehydrogenase 12.4 % 2. Potassium Ferricyanide 49.6 % 3. Non-reactive Ingredients 38.0 %	1. FAD-Glucose dehydrogenase 12.1% 2. Potassium ferricyanide 48.5% 3. Non-reactive ingredients 39.4%
Interference	Dopamine HCl > 2.3 mg/dL Gentisic Acid > 3.0 mg/dL Glutathione reduced > 35 mg/dL Hemoglobin > 10,000 mg/dL Uric Acid > 10 mg/dL Maltose > 1900 mg/dL Xylose > 9.0 mg/dL	Ascorbic acid > 3 mg/dL; Glutathione reduced >60 mg/dL; Uric Acid > 12 mg/dL
Power Saving	Turn off automatically 2 minutes after last user action / Press the main button for 3 seconds.	
Coding	Auto coding	
Monitor	LCD display	

Models	**Rightest BGMS Max Plus (New Device)**	**Rightest BGMS Max (New Device)**	**Rightest BGMS GM720 (Predicate Device) K140210**
	GE BGMS Max Plus (New Device)	**GE BGMS Max (New Device)**	
Backlight	Yes		
Color	black		
Memory Capacity	1000 blood glucose test results with date and time		
Power Supply	Two CR2032 batteries	One CR2032 battery	Two CR2032 batteries
Wireless module	Yes	No	
Battery Life	1000 Tests		600 Tests
Meter Dimension	50.0 mm x 82.0 mm x 15.5 mm		71.5 mm x 39.5 mm x14.0 mm
LCD display area	40.7 mm x 40.2 mm		25.02 mm x 32.7 mm
Meter Weight	59 ± 5g with batteries		50 ± 5 g with batteries

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

Verification and validation of test results were evaluated to establish the performance, functionality and reliability of Rightest Blood Glucose Monitoring System Max Plus. The evaluation included precision, linearity, interference, sample volume and hematocrit.

9. Discussion of Clinical Tests Performed:

Layuser Performance Study:
A User performance study with 357 participants was performed to demonstrate that lay users could obtain accurate results using the subject device. The study was performed using capillary whole blood from fingertip, palm and forearm sample sites. The study result shows substantial equivalence to comparison method.

10. Conclusions:

Results of performance evaluation of Rightest Blood Glucose Monitoring System Max, Rightest Blood Glucose Monitoring System Max Plus, GE Blood glucose monitoring System Max and GE Blood glucose monitoring System Max Plus demonstrate that the candidate devises are substantial equivalence to the predicate device, Rightest Blood Glucose Monitoring System GM720.