June 2, 2019

Bionime Corporation
c/o Feng-Yu Lee
Dynamic Biotech Inc. dba IVDD Regulatory Consultant
29122 Rancho Viejo Road, Suite 212
San Juan Capistrano, CA 92675

Re: K190564
Trade/Device Name: Rightest Blood Glucose Monitoring System GM700S
Rightest Blood Glucose Monitoring System GM700SB
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: February 22, 2019
Received: March 5, 2019

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, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
k190564

Device Name
Rightest Blood Glucose Monitoring System GM700S

Indications for Use *(Describe)*

The Rightest Blood Glucose Monitoring System GM700S consists of the Rightest Blood Glucose Monitoring Meter GM700S and the Rightest Blood Glucose Test Strips GS700.
The Rightest Blood Glucose Monitoring System GM700S 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 GM700S is intended for self-testing outside the body (in-vitro diagnostic use), by individuals with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended to be used by a single person and should not be shared.
The systems 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).

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*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

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)*
k190564

Device Name
Rightest Blood Glucose Monitoring System GM700SB

Indications for Use *(Describe)*

The Rightest Blood Glucose Monitoring System GM700SB consists of the Rightest Blood Glucose Monitoring Meter GM700SB and the Rightest Blood Glucose Test Strips GS700.
The Rightest Blood Glucose Monitoring System GM700SB 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 GM700SB is intended for self-testing outside the body (in-vitro diagnostic use), by individuals with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended to be used by a single person and should not be shared.
The systems 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).

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: k190564

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
29122 Rancho Viejo Road, Suite 212
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: May 2nd, 2019

2. Name of the Device:
Rightest Blood Glucose Monitoring System GM700S
Rightest Blood Glucose Monitoring System GM700SB

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 |

4. Device Description:

Rightest Blood Glucose Monitoring System GM700S and Rightest Blood Glucose Monitoring System GM700SB, 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 GM700S and Rightest Meter GM700SB (with Bluetooth), when used with the Rightest Test Strips GM700S, quantitatively measure glucose in fresh whole blood samples from capillary. The performance of Rightest Blood Glucose Monitoring System GM700S and Rightest Blood Glucose Monitoring System

GM700SB (with Bluetooth) are verified by the Rightest Control Solution GC700.

5. Intended Use:

(I) Rightest Blood Glucose Monitoring System 700S

The Rightest Blood Glucose Monitoring System GM700S consists of the Rightest Blood Glucose Monitoring Meter GM700S and the Rightest Blood Glucose Test Strips GS700.
The Rightest Blood Glucose Monitoring System GM700S 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 GM700S is intended for self-testing outside the body (in-vitro diagnostic use), by individuals with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended to be used by a single person and should not be shared.
The systems 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).

(II) Rightest Blood Glucose Monitoring System 700SB

The Rightest Blood Glucose Monitoring System GM700SB consists of the Rightest Blood Glucose Monitoring Meter 700SB and the Rightest Blood Glucose Test Strips GS700.
The Rightest Blood Glucose Monitoring System GM700SB 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 GM700SB is intended for self-testing outside the body (in-vitro diagnostic use), by individuals with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system is intended to be used by a single person and should not be shared.
The systems 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).

6. Predicate Device Information:

The subject devices are substantially equivalent to the brand of Rightest Blood Glucose Monitoring System noted below.

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

7. Comparison to Predicate Devices:

| | **Subject Devices** | | **Predicate Device** |
|---|---|---|---|
| **Specification** | **Rightest GM700S** | **Rightest GM700SB** (GM700S w/ Bluetooth) | **Rightest GM720** |
| Indications for Use | Same | | Quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip, palm and forearm as an aid to monitor the effectiveness of diabetes control |
| Minimum Sample Volume | 0.75 microliter | | |
| Test Time | 5 seconds | | |
| Hematocrit | 20 - 60 % | | 20 - 65 % |
| 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 | | |
| Measurement Technology | Dehydrogenase Electrochemical Sensor | | |
| Sample | Fresh capillary whole blood from fingertips, palm, or forearm. | | |
| Measuring Range | 20 - 600 mg/dL | | |
| Operating Temperature | 10 ~ 40˚C (50 ~104 ˚F) | | |
| Operating Relative Humidity | 10 ~ 90% | | |
| Monitor | LCD display | | |
| Meter Storage Conditions | -10 ~ 60˚C (14 ~140 ˚F) | | |
| Test Strip Storage Conditions | 4 ~ 30℃ (39 ~ 86 ℉), 10 - 90% relative humidity | | |
| Unit of Measurement Data | Fixed on mg/dL | | |
| Backlight | No | | Yes |
| Strip Shelf Life – Open Vial | 4 months | | |
| Control Solution | Rightest Control Solution GC700 | | |
| Interference | Ascorbic acid ≥ 3 mg/dL<br>Uric acid ≥ 10 mg/dL<br>Xylose ≥ 20 mg/dL | | Ascorbic acid ( ≥ 3 mg/dL),<br>Dopamine ( ≥1.25 mg/dL),<br>L-Dopa ( ≥2 mg/dL),<br>Xylose ( ≥10 mg/dL)<br>Uric Acid ( ≥16 mg/dL |

| | | | |
|---|---|---|---|
| Reagent | 1. FAD-Glucose dehydrogenase 12.4 %<br>2. Potassium Ferricyanide 49.6 %<br>3. Non-reactive Ingredients 38.0 % | | 1. FAD-Glucose dehydrogenase 12.1%<br>2. Potassium ferricyanide 48.5%<br>3. Non-reactive ingredients 39.4% |
| Wireless module | No | Bluetooth 4.0 (Low energy) | No |
| Power Supply | One CR2032 battery | | Two CR2032 batteries |
| Battery Life | 1000 tests | | About 600 tests |
| Meter Dimension | 82mm*45mm*15.5mm | | 71.5 mm *39.5 mm *14.0 mm |
| LCD display area | 34 mm*27.5mm | | 25.02 mm *32.7 mm |
| Meter Weight | 43.0± 5g with batteries | | 50 ± 5 g with batteries |
| Color | White/Gray | | Black |

8. Technology Characteristics:

The Rightest Blood Glucose Monitoring System GM700S, GMS700SB are electronic device that 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.

9. 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 the subject devices. The evaluation included precision, linearity, interference, sample volume, hematocrit, and operated environment.

10. Discussion of Clinical Tests Performed:

User Performance Study:

A User performance study 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. A total of 354 patients participated. The study result shows substantial equivalence to predicate device used in finger, palm and forearm position.

11. Conclusions:

Results of performance evaluation of the Rightest Blood Glucose Monitoring System subject devices demonstrate that the candidate devises are substantial equivalence to the predicate device, Rightest Blood Glucose Monitoring System GM720.