June 19, 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: K173139
Trade/Device Name: Rightest Blood Glucose Monitoring System Wiz
Rightest Blood Glucose Monitoring System Wiz Plus
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: May 15, 2018
Received: May 18, 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. 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.

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)*
k173139

Device Name
Rightest Blood Glucose Monitoring System Wiz

Indications for Use *(Describe)*
Rightest Blood Glucose Monitoring System Wiz 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 Wiz 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).

Rightest Blood Glucose Test Strip Wiz is used with Rightest Wiz Blood Glucose Meter 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.

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)*
k173139

Device Name
Rightest Blood Glucose Monitoring System Wiz Plus

Indications for Use *(Describe)*
Rightest Blood Glucose Monitoring System Wiz Plus 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 Wiz Plus 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).

Rightest Blood Glucose Test Strip Wiz is used with Rightest Blood Glucose Meter Wiz Plus 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 SMDA l990 and 21 CFR §807.92.

The assigned 510(k) number is: k173139

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: 1-949-218-0928

Date Summary Prepared: June 18th, 2018

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

Rightest Blood Glucose Monitoring System Wiz and Wiz Plus are identical with the exception of Bluetooth function for Rightest Blood Glucose Monitoring System Wiz Plus, which allows for wireless information transfer.
Rightest Blood Glucose Monitoring System Wiz and Wiz Plus 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.

5. Intended Use:

Rightest Blood Glucose Monitoring System Wiz

Rightest Blood Glucose Monitoring System Wiz 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 Wiz 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).

Rightest Blood Glucose Test Strip Wiz is used with Rightest Blood Glucose Meter Wiz 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 Wiz Plus

Rightest Blood Glucose Monitoring System Wiz Plus 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 Wiz Plus 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).

Rightest Blood Glucose Test Strip Wiz is used with Rightest Blood Glucose Meter Wiz Plus for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm.

6. Predicate Device Information:

Rightest Blood Glucose Monitoring System Wiz and Wiz Plus are substantially equivalent to the models of Rightest Blood Glucose Monitoring System noted below.

Name:	Rightest GM280 Blood Glucose Monitoring System
Device Company:	Bionime Corporation
510(K) Number:	K170143

7. Comparison to Predicate Devices:

7.1 Specification Comparison – Rightest Wiz vs. Rightest GM280

Models	**Rightest BGMS Wiz (New Device)**	**Rightest BGMS GM280 (Predicate Device)**
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 microliter	
Primary Site Testing	Fingertip	
Alternative Site Testing	Forearm, Palm	
Unit of Measurement	mg/dL	
Measuring Range	20-600 mg/dL	
Test 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℃), 10 ~ 90％ Relative Humidity	
Meter Storage Conditions	14 ~140 °F (-10 ~ 60℃)	
Test Strip Storage Condition	39 ~86 °F (4 ~ 30℃), 10-90％ relative humidity	
Test Strip Shelf Life (After Opening)	3 months	
Test Strip Reagent	Glucose Oxidase (GOD) 18.8 % Potassium Ferricyanide 37.7 % Non-reactive Ingredients 43.5 %	
Interference	Ascorbic acid > 3 mg/dL Bilirubin-conjugated >10 mg/dL Uric Acid >11.8 mg/dL	Ascorbic acid > 3 mg/dL Uric Acid > 12 mg/dL

Wireless module	No	
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	
Battery Life	1000 tests	
Power Supply	One CR2032 battery	
Memory Capacity	1000 blood glucose test results with date and time	500 blood glucose test results with date and time
Meter Dimension	50.0 mm x 82.0 mm x 15.5 mm	82mm*45mm*15.5mm
LCD display area	40.7 mm x 40.2 mm	34 mm*27.5mm
Meter Weight	59 ± 5g with batteries	43.0± 5g with batteries
Color	white/black	white/gray

7.2 Specification Comparison – Rightest Wiz Plus vs. Rightest GM280

Models	**Rightest BGMS Wiz Plus (New Device)**	**Rightest BGMS GM280 (Predicate Device)**
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 microliter	
Primary Site Testing	Fingertip	
Alternative Site Testing	Forearm, Palm	
Unit of Measurement	mg/dL	
Measuring Range	20-600 mg/dL	
Test 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 Condition	39 ~86 °F (4 ~ 30°C), 10-90％ relative humidity	
Test Strip Shelf Life (After Opening)	3 months	
Test Strip Reagent	Glucose Oxidase (GOD) 18.8 % Potassium Ferricyanide 37.7 % Non-reactive Ingredients 43.5 %	
Interference	Ascorbic acid > 3 mg/dL Bilirubin-conjugated >10 mg/dL Uric Acid >11.8 mg/dL	Ascorbic acid > 3 mg/dL Uric Acid > 12 mg/dL
Wireless Module	Yes, via low energy Bluetooth	
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	
Battery Life	1000 tests	
Memory Capacity	1000 blood glucose test results with date and time	500 blood glucose test results with date and time
Power Supply	Two CR2032 batteries	One CR2032 battery
Meter Dimension	50.0 mm x 82.0 mm x 15.5 mm	82mm*45mm*15.5mm
LCD display area	40.7 mm x 40.2 mm	34 mm*27.5mm
Meter Weight	59 ± 5g with batteries	43.0± 5g with batteries
Color	white/black	white/gray
Bluetooth	Yes	No

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

Verification and validation activities were performed on Rightest BGMS Wiz/Wiz Plus to establish performance, functionality, and reliability of the device system. Evaluations included precision, linearity, interference, sample volume and hematocrit.

9. 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. The study result shows substantial equivalence to predicate device used in finger, palm and forearm position.

The study results demonstrate that the usability of Rightest Blood Glucose Monitoring System Wiz and Wiz Plus.

10. Conclusions:

Results of performance evaluation of Rightest Blood Glucose Monitoring System Wiz and Wiz Plus demonstrate that the device is substantially equivalent to the predicate device Rightest GM280 Blood Glucose Monitoring System.