January 19, 2024

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

Re: K231192
Trade/Device Name: RIGHTEST Blood Glucose Monitoring System Max Tel
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: April 27, 2023
Received: April 27, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231192

Device Name
RIGHTEST Blood Glucose Monitoring System Max Tel

Indications for Use *(Describe)*
RIGHTEST Blood Glucose Monitoring System Max Tel 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 Tel 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 Tel is comprised of the RIGHTEST Meter Max Tel and the RIGHTEST Blood Glucose Test Strip 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.

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"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."

510(K) SUMMARY

This summary of 5l0(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: __ K231192_

1. Submitter's Identification:

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c/o Dynamic Biotech Inc. dba IVDD Regulatory Consultant
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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: January 18, 2024

2. Name of the Device:
RIGHTEST Blood glucose monitoring System Max Tel

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 Max Tel consists of the following devices: Blood Glucose Meter, Blood Glucose Test Strip, Control Solution, Lancing Device and Sterile Lancets. The RIGHTEST Blood Glucose Test Strip Max is the same as Test Strip Max cleared in K173638.The Blood Glucose Meter, Blood Glucose Test Strips, and Lancing Device are manufactured by BIONIME Corporation.

RIGHTEST Blood Glucose Meter Max Tel, when used with the RIGHTEST Blood Glucose Test Strips Max, quantitatively measure glucose in fresh whole blood samples from capillary. The performance of RIGHTEST Blood Glucose Monitoring System Max Tel is verified by the RIGHTEST Control Solution GC700.
The glucose measurement is achieved by using the amperometric detection method. The test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the test strip. The blood sample is pulled into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD-glucose dehydrogenase and the mediator. Electrons are generated, producing a current that is positive correlation to the glucose concentration in the sample. After the reaction time, the glucose concentration in the sample is displayed.

5. Intended Use:

RIGHTEST Blood Glucose Monitoring System Max Tel 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 Tel 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 Tel is comprised of the RIGHTEST Meter Max Tel and the RIGHTEST Blood Glucose Test Strip Max.

6. Predicate Device Information:

RIGHTEST Blood Glucose Monitoring System Max Tel is substantially equivalent to the brand of RIGHTEST Blood Glucose Monitoring System Max Plus noted as 6.1.

6.1

Name:	RIGHTEST Blood Glucose Monitoring System Max Plus
Device Company:	Bionime Corporation
510(K) Number:	K173638

7. Comparison to Predicate Devices:

Models	**RIGHTEST BGMS Max Tel (New Device)**	**Rightest BGMS Max Plus (Predicate Device) K173638**
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 ~131 ℉ (-10 ~ 55℃)	14 ~140 ℉ (-10 ~ 60℃)
Test Strip Shelf Life (After Opening)	4 months	
Test Strip Reagent	1. FAD-Glucose dehydrogenase 12.4 % 2. Potassium Ferricyanide 49.6 % 3. Non-reactive Ingredients 38.0 %	
Interference	(Test according to FDA SMBG OTC guidance 2020) Ascorbic Acid ≥ 3 mg/dL Conjugated Bilirubin ≥ 30 mg/dL Uric Acid ≥ 12 mg/dL Xylose ≥ 8 mg/dL	(Test according to FDA SMBG OTC guidance 2016) 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
Power Saving	Turns off automatically after the default time 30 seconds or be set by the user. To turn off manually, press the main button for 2 seconds.	Turn off automatically 2 minutes after last user action / Press the main button for 3 seconds.
Coding	Auto coding	
Monitor	Color LCD	LCD
Backlight	No	
Color	black	
Power Supply	Non-replaceable and Rechargeable Lithium battery (3.7 V)	Two CR2032 batteries
Data Transmission	N/A	Bluetooth

Memory Capacity	1000 blood glucose test results with date and time	500 blood glucose test results with date and time
Meter Dimension	60.0 mm x 10.0 mm x 14.0 mm	50.0 mm x 82.0 mm x 15.5 mm
LCD Display Area	2.8-inch touch panel	40.7 mm x 40.2 mm
Meter Weight	95 ± 5g with batteries	59 ± 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 Tel. The evaluation included precision, linearity, interference, sample volume, hematocrit and other required item specified in the FDA SMBG OTC guidance.
All laboratory studies that the acceptance criteria were met. Therefore, the performances from these laboratory studies were acceptable

No.	Test/Validation Item
1	Linearity Evaluation Study
2	Lay user evaluation (Usability Evaluation)
3	EMC Testing
4	Electrical Safety Testing
5	Precision (Within-Run and Intermediate)
6	Specimen Volume Study (Short Sample Detection)
7	Interference Study
8	Operated Altitude study
9	Operated Temperature and Humidity study
10	Hematocrit study
11	Closed Vial Stability Study (Real-Time and Accelerated)
12	Opened Vial Stability Study (Real-Time and Accelerated included)
13	Robustness Cleaning and Disinfection
14	Virucidal Efficacy Report
15	Intermittent Sampling and Sample Perturbation
16	Used Test Strip and Interrupt of Testing
17	Evaluation of Error Message
18	Measure Time Test Function
19	Evaluation of Auto Code Reliability
20	Evaluation of Average Function
21	Battery Power Error and Temperature Error
22	Hi Lo Display
23	Memory Function
24	Power Saving Function
25	Vibration Testing

26	Transportation
27	Software Safety Analysis

9. Discussion of Clinical Tests Performed:

User Performance Study:

A User performance study with 370 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 used in finger, palm and forearm position.

Layperson	Fingertip:	Palm	Forearm
Glucose range	52.5~537	52.5~537	52.5~537
Test number	370	370	370

System accuracy
RIGHTEST Blood Glucose Monitoring System Max Tel total finger results 98.6% are within the reference bias and 15%, 100% are within the reference bias 20%.
RIGHTEST Blood Glucose Monitoring System Max Tel total palm results 97.2% are within the reference bias and 15%, 100% are within the reference bias 20%.
RIGHTEST Blood Glucose Monitoring System Max Tel total forearm results 97.65% are within the reference bias and 15%, 100% are within the reference bias 20%.

	Finger	Palm	Forearm
Accurate results (+/-15%)	365 out of 370	360 out of 370	361 out of 370
More Accurate results (+/-10%)	333 out of 370	323 out of 370	316 out of 370
Most Accurate results (+/-5%)	231 out of 370	211 out of 370	226 out of 370

10. Conclusions:

Results of performance evaluation of RIGHTEST Blood Glucose Monitoring System Max Tel demonstrate that the device is substantially equivalent to the predicate device, Rightest Blood Glucose Monitoring System MAX Plus.