November 4, 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, California 92675

Re: K240637
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: October 3, 2024
Received: October 3, 2024

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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)*
K240637

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.

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:

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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: K240637

1. Submitter's Identification:

BIONIME CORPORATION
NO 100, Sec. 2, Daqing St., South Dist., 40242 Taichung City, Taiwan
Contact Person: __Kay Wu_____
Phone Number: 886-4-23692388, Ext:5898
FAX Number: 886-4-22617568

c/o Dynamic Biotech Inc. dba 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: November 1, 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 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:	K231192

7. Comparison to Predicate Devices:

Models	**RIGHTEST BGMS Max Tel (New Device)**	**RIGHTEST BGMS Max Tel (Predicate Device) K231192**
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℃)	
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	Ascorbic Acid ≥ 3 mg/dL Conjugated Bilirubin ≥ 30 mg/dL Uric Acid ≥ 12 mg/dL Xylose ≥ 8 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.	
Coding	Auto coding	
Monitor	Color LCD	
Backlight	No	
Color	black	
Power Supply	Non-replaceable and Rechargeable Lithium battery (3.7 V)	
Memory Capacity	1000 blood glucose test results with date and time	
Meter Dimension	60.0 mm x 10.0 mm x 14.0 mm	
LCD Display Area	2.8-inch touch panel	
Meter Weight	95 ± 5g with batteries	
Data Transmission	LTE network	NA
Measuring Range	20 - 600 mg/dL (1.1 - 33.3 mmol/L)	50 - 550 mg/dL (2.8 - 30.6 mmol/L)

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 Hi and Lo Display, Extreme Glucose Study, Software Safety Analysis, FCC report, LTE function and Cybersecurity Evaluation 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	Hi Lo Display
2	The Extreme Glucose Study
3	Software Safety Analysis (FCC report, LTE function, Cybersecurity Evaluation)

Hi Lo Display
The measurement range has been adjusted, and the system displayed a notification—indicating "Hi" or "Lo"—for results that fall outside the established range.

The Extreme Glucose Study
A study conducted on glucose performance using both natural and modified blood samples. The results demonstrated compliance with the FDA's accuracy guidelines for Over-the-Counter (OTC) Self-Monitoring Blood Glucose (SMBG) systems.

Software Safety Analysis
Software adjustments were made to enable LTE functionality and adjusted the measurement range. The LTE function was validated through both FCC compliance testing and laboratory testing. As LTE functionality introduced cybersecurity considerations, we ensured compliance with the FDA's guidance on the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

9. Conclusions:

Results of performance evaluation of RIGHTEST Blood Glucose Monitoring System Max Tel that had no impacts to BGM measurement was conducted to support substantially equivalent to the predicate device, RIGHTEST Blood Glucose Monitoring System MAX Tel.