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

Re: K170143  
Regulation Number: 21 CFR 862.1345  
Regulation Name: Glucose test system  
Regulatory Class: Class II  
Product Code: NBW  
Dated: May 30, 2017  
Received: June 7, 2017  

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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
Indications for Use

The Rightest Blood Glucose Monitoring System GM280B 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 GM280B is intended to be used by a single person and should not be shared.

The Rightest Blood Glucose Monitoring System GM280B 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. The Rightest Blood Glucose Monitoring System 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 Test Strip GS280 is used with Rightest meter GM280B 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.”
Indications for Use

The GE Blood Glucose Monitoring System 182 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 GE Blood Glucose Monitoring System 182 is intended to be used by a single person and should not be shared.

The GE Blood Glucose Monitoring System 182 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. The GE Blood Glucose Monitoring System 182 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 Strip 180 is used with GE Blood Glucose Monitoring Meter 182 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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Indications for Use

The Rightest Blood Glucose Monitoring System GM280 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 GM280 is intended to be used by a single person and should not be shared.

The Rightest Blood Glucose Monitoring System GM280 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. The Rightest Blood Glucose Monitoring System 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 Test Strip GS280 is used with Rightest meter GM280 for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.
Indications for Use

Device Name
GE Blood glucose monitoring System 180

Indications for Use (Describe)
The GE Blood Glucose Monitoring System 180 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 GE Blood Glucose Monitoring System 180 is intended to be used by a single person and should not be shared.

The GE Blood Glucose Monitoring System 180 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. The GE Blood Glucose Monitoring System 180 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 Strip 180 is used with GE Blood Glucose Monitoring Meter 180 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 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

The assigned 510(k) number is: k170143

1. **Submitter's Identification:**

   BIONIME CORPORATION  
   NO 100, Sec. 2, Daqing St., South Dist., 40242 Taichung City, Taiwan  
   Contact Person: Mr. Roy Huang  
   Phone Number: 886-4-23692388  
   FAX Number: 886-4-22617568

   Date Summary Prepared: July 6, 2017

2. **Name of the Device:**

   Rightest Blood Glucose Monitoring System GM280  
   Rightest Blood Glucose Monitoring System GM280B  
   GE Blood Glucose Monitoring System 180  
   GE Blood Glucose Monitoring System 182

3. **Common or Usual Name:** Glucose test system

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Classification</th>
<th>Regulation Section</th>
<th>Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>NBW; System, Test, Blood Glucose, Over-the-Counter</td>
<td>Class II</td>
<td>21 CFR 862.1345</td>
<td>Clinical Chemistry 75</td>
</tr>
</tbody>
</table>

4. **Device Description:**

   The Rightest and GE Blood Glucose Monitoring System series 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.


   The GE Blood Glucose Meter 180 and GE Blood Glucose Meter 182, when used with the GE Blood Glucose Test Strips 180, quantitatively measure glucose in fresh capillary whole

5. **Intended Use:**

**Rightest Blood Glucose Monitoring System GM280**

The Rightest Blood Glucose Monitoring System GM280 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 GM280 is intended to be used by a single person and should not be shared. The Rightest Blood Glucose Monitoring System GM280 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. The Rightest Blood Glucose Monitoring System 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 Test Strip GS280 is used with Rightest meter GM280 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 GM280B**

The Rightest Blood Glucose Monitoring System GM280B 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 GM280B is intended to be used by a single person and should not be shared. The Rightest Blood Glucose Monitoring System GM280B 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. The Rightest Blood Glucose Monitoring System 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 Test Strip GS280 is used with Rightest meter GM280B for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

**GE Blood Glucose Monitoring System 180**

The GE Blood Glucose Monitoring System 180 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 GE Blood Glucose Monitoring System 180 is intended to be used by a single person and should not be shared. The GE Blood Glucose Monitoring System 180 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. The GE Blood Glucose Monitoring System 180 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 Strip 180 is used with GE Blood Glucose Monitoring Meter 180 for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

**GE Blood Glucose Monitoring System 182**

The GE Blood Glucose Monitoring System 182 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 GE Blood Glucose Monitoring System 182 is intended to be used by a single person and should not be shared.

The GE Blood Glucose Monitoring System 182 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. The GE Blood Glucose Monitoring System 182 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 Strip 180 is used with GE Blood Glucose Monitoring Meter 182 for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

6. **Predicate Device Information:**


- **Name:** GE333 Blood Glucose Monitoring System
- **Device Company:** Bionime Corporation
- **510(K) Number:** K143387
7. **Comparison to Predicate Devices:**

**Specification Comparison**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Subject Devices</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rightest GM280</td>
<td>Rightest GM280B</td>
</tr>
<tr>
<td></td>
<td>GE180</td>
<td>GE182</td>
</tr>
<tr>
<td></td>
<td>GE333</td>
<td></td>
</tr>
<tr>
<td>Indications for Use</td>
<td>Over-The-Counter: For single-patient use only, in-vitro diagnostic use only by individuals with diabetes at home</td>
<td></td>
</tr>
<tr>
<td>Measurement Technology</td>
<td>Glucose Oxidase</td>
<td>Electrochemical Sensor</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample Type</td>
<td>Capillary whole blood</td>
<td></td>
</tr>
<tr>
<td>Minimum Sample Volume</td>
<td>0.75 μL</td>
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<tr>
<td>Primary Site Testing</td>
<td>Fingertip</td>
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<tr>
<td>Alternative Site Testing</td>
<td>Forearm, Palm</td>
<td></td>
</tr>
<tr>
<td>Unit of Measurement</td>
<td>mg/dL</td>
<td></td>
</tr>
<tr>
<td>Measuring Range</td>
<td>20-600 mg/dL</td>
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<tr>
<td>Measuring Time</td>
<td>5 seconds</td>
<td></td>
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<tr>
<td>Hematocrit</td>
<td>20-60 %</td>
<td></td>
</tr>
<tr>
<td>Control Solution</td>
<td>3 levels (Level 1, 2, and 4)</td>
<td>Rightest Control Solution GC550</td>
</tr>
<tr>
<td>Maximum Altitude</td>
<td>10745 feet (3275 m)</td>
<td></td>
</tr>
<tr>
<td>Operating Conditions</td>
<td>Temperature 50 ~104 °F (10 ~ 40°C), 10 ~ 90% Relative Humidity</td>
<td></td>
</tr>
<tr>
<td>Meter Storage Conditions</td>
<td>14 ~140 °F (-10 ~ 60°C)</td>
<td></td>
</tr>
<tr>
<td>Test Strip Storage Conditions</td>
<td>39 ~86 °F (4 ~ 30°C), 10-90% relative humidity</td>
<td></td>
</tr>
<tr>
<td>Test Strip Shelf Life (After Opening)</td>
<td>3 months</td>
<td></td>
</tr>
<tr>
<td>Interference</td>
<td>Ascorbic acid &gt; 3 mg/dL</td>
<td>Ascorbic acid ≥ 5 mg/dL</td>
</tr>
<tr>
<td></td>
<td>Glutathione reduced &gt;60 mg/dL</td>
<td>Cholesterol ≥ 600 mg/dL</td>
</tr>
<tr>
<td></td>
<td>Uric Acid &gt; 12 mg/dL</td>
<td>Uric acid ≥ 10 mg/dL</td>
</tr>
</tbody>
</table>
8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:


9. Discussion of Clinical Tests Performed:

System Accuracy Study:
The system accuracy study of the Rightest Blood Glucose Monitoring System GM280 was performed by comparing capillary and venous whole blood (plasma equivalent) glucose values on the Rightest Blood Glucose Meter GM280 with glucose values on lab instrument YSI 2300 Plus Glucose Analyzer.
A total of 104 patients participated. The study results demonstrate that the accuracy of Rightest Blood Glucose Monitoring System GM280 met the acceptance criteria.

**User Performance Study:**
The user performance study was performed to demonstrate that English speaking and reading lay users across all educational backgrounds can easily understand and follow the labeling/user instructions to obtain accurate results while using Rightest Blood Glucose Monitoring System GM280B.

A total of 135 subjects participated. The study results demonstrate that the user accuracy and ease of use (via participant questionnaire scoring) Rightest Blood Glucose Monitoring System GM280B meet the acceptance criteria.

10. **Conclusions:**