November 4, 2022

Apex BioTechnology Corp.
Lisa Liu
Manager of Quality Assurance Division
No. 7, Li-Hsin Road V, Hsinchu Science Park
Hsinchu, 30078
Taiwan

Re: K220421
Trade/Device Name: BGM039 Blood Glucose Monitoring System
BGM039 Link Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: July 20, 2022
Received: July 20, 2022

Dear Lisa Liu:

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/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 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 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,

Paula Caposino -S
Digitally signed by Paula Caposino -S
Date: 2022.11.04 10:26:19 -04'00'

Paula V. Caposino, Ph.D.
Acting Deputy Director
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)*
K220421

Device Name
BGM039 Blood Glucose Monitoring System

Indications for Use *(Describe)*
The BGM039 Blood Glucose Monitoring System is comprised of the BGM039 Blood Glucose Meter and the BGM039 Blood Glucose Test Strips.
The BGM039 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). It is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control and should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220421

Device Name
BGM039 Link Blood Glucose Monitoring System

Indications for Use *(Describe)*
The BGM039 Link Blood Glucose Monitoring System is comprised of the BGM039 Link Blood Glucose Meter and the BGM039 Blood Glucose Test Strips.
The BGM039 Link Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). It is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control and should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

Type of Use *(Select one or both, as applicable)*

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510(k) Summary

510(k) number	K220421
Submitter	Apex Biotechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN)
Contact Person	Lisa Liu Manager of Quality Assurance Division Apex Biotechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN) email: lisaliu@apexbio.com Phone: 011-886-3-5641952 FAX: 011-886-3-5678021
Date Prepared	Feb 08, 2022
Trade Names	BGM039 Blood Glucose Monitoring System BGM039 Link Blood Glucose Monitoring System
Classification	Glucose test system, 21 CFR 862.1345, Class II
Product Codes	NBW
Predicate Devices	GlucoSure HT Plus Blood Glucose Monitoring System (K202885)
Device Description	BGM039 brand of Blood Glucose Monitoring System is designed to have two variation models, BGM039 Blood Glucose Monitoring System and BGM039 Link Blood Glucose Monitoring System. BGM039 Blood Glucose Monitoring System is the models with all the changes implemented with exception to the addition of a Bluetooth module, whereas, BGM039 Link Blood Glucose Monitoring System is implemented with all of the changes stated in the submission. The two meters use the same BGM039 Test Strip and Contrex Plus 4 Control Solution. This Premarket Notification (510(k)) is intended to demonstrate that the candidate devices to be marketed is safe and effective as the predicate device, GlucoSure HT Plus Blood Glucose Monitoring System, K202885. BGM039 Blood Glucose Monitoring System and BGM039 Link Blood Glucose Monitoring System consists of the blood glucose meter and single use test strips. It is used for testing of blood glucose by self-testers at home.

510(k) Summary (Continued)

Intended Use	BGM039 Blood Glucose Monitoring System The BGM039 Blood Glucose Monitoring System is comprised of the BGM039 Blood Glucose Meter and the BGM039 Blood Glucose Test Strips. The BGM039 Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). It is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control and should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.
	BGM039 Link Blood Glucose Monitoring System The BGM039 Link Blood Glucose Monitoring System is comprised of the BGM039 Link Blood Glucose Meter and the BGM039 Blood Glucose Test Strips. The BGM039 Link Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). It is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control and should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.
Comparison of Technological Characteristics	The BGM039 Blood Glucose meter and BGM039 Link Blood Glucose meter uses the same test strip and test algorithm as the predicate. The changes was for • LCD patter modification • Case change: o Dimensions of the meter were changed from 96Lx58Wx16H (mm) to 86Lx58Wx18H (mm). o Remove Strip ejection button and USB port. o Button positioning was changed from the front to the sides of the meter. • Case color change o BGM039 Blood Glucose meter: The color of upper case and button were changed from blue to black；the color of lower case and battery cover were changed from white to black.

	○ BGM039 Link Blood Glucose meter: The color of upper case was changed from blue to silver；the color of lower case and battery cover were changed from white to silver；the color of button was changed from blue to black. • PCB circuit change ○ MCU change. ○ Addition of a Bluetooth module to the BGM039 Link Blood Glucose Monitoring System for the wireless transfer of data to mobile devices. ○ Remove USB connector, relocation of button from up to meter side and relocation of strip holder from up to the bottom of the meter. • Software change: ○ Add Bluetooth function/display on LCD and remove the USB transmission flow. ○ Added error massage for BGM039 Link Blood Glucose Monitoring System. Err5: Meter fails in Bluetooth status check, Err6: Bluetooth pairing is fail, Err7: Data transmission via Bluetooth is interrupted, Err8: Bluetooth disconnection between meter and mobile device occurred during transmission procedure. • Trade name of the system changed from GlucoSure HT Plus Blood Glucose Monitoring System to BGM039 Blood Glucose Monitoring System and BGM039 Link Blood Glucose Monitoring System. ○ Meter name change from GlucoSure HT Plus meter to BGM039 meter and BGM039 Link meter. ○ Strip name change from GlucoSure HT blood glucose strip to BGM039 blood glucose strip. The BGM039 Blood Glucose Monitoring System and BGM039 Link Blood Glucose Monitoring System shares identical glucose test strips with GlucoSure HT Plus Blood Glucose Monitoring System, but only change in brand name from GlucoSure HT Blood Glucose Test Strips to BGM039 Blood Glucose Test Strips.

Non-Clinical Testing	Testing was conducted as follows: Robustness test, drop test, battery life test, linearity test, intermediate precision, within-run precision, accuracy test, usability study, EMC and Electrical Safety and Software verification and validation including cybersecurity management, and results demonstrate substantial equivalence to the predicate system.
Clinical Testing	No clinical testing was conducted.
Conclusion	Testing showed that the BGM039 Blood Glucose Monitoring System and BGM039 Link Blood Glucose Monitoring System perform in a substantially equivalent manner to that of the predicate. We conclude that the candidate devices are substantially equivalent to the predicate device.