March 29, 2022

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

Re: K213887
Trade/Device Name: GAL-1A Plus Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: December 10, 2021
Received: December 13, 2021

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,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K213887

Device Name
GAL-1A Plus Blood Glucose Monitoring System

Indications for Use *(Describe)*
GAL-1A Plus Blood Glucose Monitoring System: GAL-1A Plus Blood Glucose Monitoring System is comprised of the GAL-1A Plus Blood Glucose Meter, the GAL-1A Blood Glucose Test Strips.
The GAL-1A Plus 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). Testing is done outside the body (In Vitro diagnostic use). It is indicated for lay use by people with diabetes, as an aid to monitoring levels in Diabetes Mellitus 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.

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510(k) Summary

510(k) number	K213887
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	November 30, 2021
Trade Names	GAL-1A Plus Blood Glucose Monitoring System
Classification	Glucose test system, 21 CFR 862.1345, Class II
Product Codes	NBW
Predicate Devices	GAL-1A Blood Glucose System (k113208)
Device Description	The GAL-1A Plus blood glucose monitoring system consists of the GAL-1A Plus meter and GAL-1A Test Strips. It is used for testing of blood glucose by self-testers at home.
Intended Use	GAL-1A Plus Blood Glucose Monitoring System: GAL-1A Plus Blood Glucose Monitoring System is comprised of the GAL-1A Plus Blood Glucose Meter, the GAL-1A Blood Glucose Test Strips. The GAL-1A Plus 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). Testing is done outside the body (In Vitro diagnostic use). It is indicated for lay use by people with diabetes, as an aid to monitoring levels in Diabetes Mellitus 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 GAL-1A Plus Blood Glucose meter uses the same test strip and test algorithm as the predicate. The changes was for • Case shape change: Modify the shape of the meter from rectangle to oval. Dimensions of the meter were changed from 76Lx45Wx14H (mm) to 77Lx51Wx14H (mm). • The color of case was changed from black and white to gray.
Non-Clinical Testing	Disinfection performance (robustness of meter to multiple cleanings and disinfections) was conducted. Results demonstrate substantial equivalence to the predicate system.
Clinical Testing	No clinical testing was conducted.
Conclusion	Testing showed that the modified GAL-1A Plus Blood Glucose Monitoring Systems are substantially equivalent to the predicate.