DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 6, 2015

APEX BIOTECHNOLOGY CORP.
HSUE-MEI LEE
MANAGER OF QUALITY ASSURANCE DEPARTMENT
NO. 7, LI-HSIN RD. V, HSINCHU SCIENCE PARK
HSINCHU, TAIWAN, ROC

Re: K142689
Trade/Device Name: GAL-1F Blood Glucose Monitoring System,
GAL-1F Pro Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CGA, NBW
Dated: July 7, 2015
Received: July 8, 2015

Dear Hsue-Mei 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 Parts 801 and 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 regulations (21 CFR Parts 801 and 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 yours,

Courtney H. Lias -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k142689

Device Name
GAL-1F Blood Glucose Monitoring System

Indications for Use *(Describe)*
The GAL-1F 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 blood glucose 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.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k142689

Device Name
GAL-1F Pro Blood Glucose Monitoring System

Indications for Use *(Describe)*
The GAL-1F Pro 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 to be used for multiple patients in a clinical setting by healthcare professionals, as an aid to monitoring blood glucose levels in Diabetes Mellitus. This system is only used with single-use, auto-disabling lancets. 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)

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510(k) Summary

Submitter	Hsue-mei Lee Manager of Quality Assurance Department Apex BioTechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN) email: hsue-mei@apexbio.com Phone: 011-886-3-5641952 FAX: 011-886-3-5678302
Contact Person	Hsue-mei Lee Manager of Quality Assurance Department Apex BioTechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN) email: hsue-mei@apexbio.com Phone: 011-886-3-5641952 FAX: 011-886-3-5678302
Date Prepared	Aug 04, 2015
Trade Names	GAL-1F Blood Glucose Monitoring System GAL-1F Blood Glucose Test Strips GAL-1F Pro Blood Glucose Monitoring GAL-1F Pro Blood Glucose Test Strips
Classification	Glucose test system, 21 CFR 862.1345, Class II
Product Codes	CGA, NBW
Predicate Devices	GAL-1E and GAL-1E Multi (k113547) Blood Glucose Monitoring Systems
Device Description	The GAL-1F blood glucose monitoring system consists of the GAL-1F meter and GAL-1F Test Strips. It is used for testing of blood glucose by self-testers at home. The GAL-1F Pro blood glucose monitoring system consists of the GAL-1F Pro meter and GAL-1F Pro Test Strips. It is used for testing of blood glucose by professional testers in healthcare facilities. The GAL-1F and GAL-1F Pro systems are identical other than trade names and details of product labeling.

Intended Use	The GAL-1F 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 blood glucose 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. The GAL-1F Pro 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 to be used for multiple patients in a clinical setting by healthcare professionals, as an aid to monitoring blood glucose levels in Diabetes Mellitus. This system is only used with single-use, auto-disabling lancets. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.
Comparison of Technological Characteristics	The GAL-1F and GAL-1F Pro meters uses the same test strip, test strip holder, and test algorithm as the predicate. The test strip holder has been moved from the top of the predicate meter to the bottom of the new meter and the test strip ejection mechanism of the predicate has been eliminated. Software has been modified to support data download functionality.
Non-Clinical Testing	Software verification and validation, linearity and detection limit testing, EMC and Electrical Safety testing, and drop testing were done. Disinfection and "robustness" testing were done to qualify several recommended disinfection solutions. Results demonstrate substantial equivalence to the predicate device.
Clinical Testing	An accuracy user study was performed with blood testing by 114 self-testers and with professional testing. 106 unaltered samples were tested by self-testers. An Ease-of-Use and Ease-of-Understanding (of the instructions for use) questionnaire were administered. Results demonstrate substantial equivalence to the predicate.
Conclusion	Clinical and non-clinical testing show that the GAL-1F / GAL-1F Pro Blood Glucose Monitoring System perform in a substantially equivalent manner to that of the predicate device. We conclude that the GAL-1F / GAL-1F Pro systems are substantially equivalent to the predicate.