K113547

MAR 2 8 2012

510(k) Summary

Submitter:	Apex Biotechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN)
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Date Prepared:	March 22, 2012
Trade Names:	GAL-1E Blood Glucose Monitoring System GAL-1E Blood Glucose Test Strips GAL-1E Multi Blood Glucose Monitoring System GAL-1E Multi Blood Glucose Test Strips
Classification:	Glucose test system, 21 CFR 862.1345, Class II
Product Codes:	CGA, NBW
Predicate Device:	GAL-1C Blood Glucose Monitoring System (k102816) GAL-1C Blood Glucose Test Strip (k102816)
Device Description:	The GAL-1E blood glucose meter and GAL-1E test strips are used for testing of blood glucose. There is one version for self-testers at home and a second version ("GAL-1E Multi") for professional use. Contrex Plus III Glucose Control Solutions are used for quality control testing of the systems.

510(k) Summary (Continued)

Intended Use:	GAL-1E Blood Glucose Monitoring System The GAL-1E 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. GAL-1E Blood Glucose Test Strips The GAL-1E Blood Glucose Test Strips are to be used with the GAL-1E Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). They are not indicated for the diagnosis or screening of diabetes or for neonatal use. GAL-1E Multi Blood Glucose Monitoring System The GAL-1E Multi 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 levels in Diabetes Mellitus. This system is only used with single-use, auto-disabling lancing device. It is not indicated for the diagnosis or screening of diabetes or for neonatal use. GAL-1E Multi Blood Glucose Test Strips The GAL-1E Multi Blood Glucose Test Strips are to be used with the GAL-1E Multi Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). They are not indicated for the diagnosis or screening of diabetes or for neonatal use. They are indicated in a clinical setting to be used for multiple patients by healthcare professionals. This system is only used with single-use, auto-disabling lancing devices.

510(k) Summary (Continued)

Comparison of Technological Characteristics:	The GAL-1E and GAL-1E Multi meters have been modified relative to the predicate by orienting the Liquid Crystal Display (LCD) vertically and rearranging its icons, adding a strip ejection button, plus altering the meter case to accommodate the LCD change. The GAL-1E and GAL-1E Multi meters use the same test algorithm as the predicate meter. The GAL-1E and GAL-1E Multi test strips are identical to their predicate devices.
Non-Clinical Testing:	Testing was conducted as follows: EMC and Electrical Safety, drop testing, disinfection performance (robustness of meter to multiple cleanings and disinfections), software verification and validation, and linearity testing with validation of Lo/Hi detection. Disinfection testing with Dispatch wipes was done using a Hepatitis B test model. Results demonstrate substantial equivalence to the predicate system.
Clinical Testing	An accuracy study was conducted with professional testing. User study data were discussed. Results demonstrate substantial equivalence to the predicate system.
Conclusion:	Clinical and non-clinical testing demonstrated that the GAL-1E, and GAL-1E Multi, systems perform in a substantially equivalent manner to that of the predicate. We conclude that the GAL-1E and GAL-1E Multi systems are substantially equivalent to the predicate system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

MAR 28 2012

Apex Biotechnology Corp.
c/o Dr. Bruce A. MacFarlane
Senior Principal Scientist
4050 Olson Memorial Hwy, Suite 450
Minneapolis, MN, 55422 USA

Re: k113547
Trade/Device Name: GAL-1E Blood Glucose Monitoring System and GAL-1E Multi Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: II
Product Code: CGA, NBW
Dated: March 22, 2012
Received: March 23, 2012

Dear Dr. MacFarlane,

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): k113547

Device Name: GAL-1E Blood Glucose Monitoring System

Indications for Use:

The GAL-1E 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.

The GAL-1E Blood Glucose Test Strips are to be used with the GAL-1E Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). They are not indicated for the diagnosis or screening of diabetes or for neonatal use.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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Indications for Use Statement

510(k) Number (if known): k113547

Device Name: GAL-1E Multi Blood Glucose Monitoring System

Indications for Use:

The GAL-1E Multi 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 levels in Diabetes Mellitus. This system is only used with single-use, auto-disabling lancing device. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

The GAL-1E Multi Blood Glucose Test Strips are to be used with the GAL-1E Multi Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). They are not indicated for the diagnosis or screening of diabetes or for neonatal use. They are indicated in a clinical setting to be used for multiple patients by healthcare professionals. This system is only used with single-use, auto-disabling lancing devices.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___ X ____ (21 CFR 801 Subpart C)

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