510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k113547

B. Purpose for Submission:

Modified Device --- Addition of a strip ejection button to a previously cleared blood glucose meter (k102816)

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose oxidase

E. Applicant:

Apex Biotechnology Corp

F. Proprietary and Established Names:

GAL-1E Blood Glucose Monitoring System

GAL-1E Multi Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
CGA –Glucose oxidase, glucose	Class II	21 CFR § 862.1345	75-Chemistry
NBW – system, test, blood glucose, over the counter	Class II	21 CFR § 862.1345	75-Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for 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.

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.

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.

3. Special conditions for use statement(s):
Alternative site testing (palm and forearm) can be used only during steady-state blood glucose conditions.

AST should not be used to calibrate CGMs or used in insulin dosing calculations

Not for use on critically ill patients, patients in shock, dehydrated patients, hypotensive patients or hyperosmolar patients.

Not indicated for the diagnosis or screening of diabetes or for neonatal use.

Single-patient use system should not be shared

Multiple-patient use system only for use with single-use, auto disabling lancing devices

4. Special instrument requirements:

   The GAL-1E Blood Glucose Meter
   The GAL-1E Multi Blood Glucose Meter

I. Device Description:

The GAL-1E and GAL-1E Multi Blood Glucose Monitoring System Starter Kits consists of the following components: a glucose test strip vial containing 25 test strips, a GAL-1E/GAL-1E Multi Blood Glucose meter, one bottle of glucose control solution, a lancet device, a clear cap for alternative site testing, lancets, Instructions for Use (test strip, control solution), User's Guide, Log Book, carrying case, battery, and a wallet.

The following can be purchased as separate individual products for use with the GAL-1E Blood Glucose Meter: one vial containing 25 test strips per box, 2 levels of control solution per box (Level 1 & 2, Level low & Level 2), and lancets.

1. Predicate device name(s):

   GAL-1C Blood Glucose Monitoring System

2. Predicate K number(s):

   k102816

3. Comparison with predicate:

Similarities and Differences of the Blood Glucose System		
Item	GAL-1C Blood Glucose Monitoring System (predicate device) k102816	GAL-1E and GAL-1E Multi Blood Glucose Monitoring System (candidate device)
Intended Use/ Indications for Use	For the quantitative measurement of glucose in fresh capillary whole blood	Same
Setting	Single patient use	Single and multiple patient use
Detection method	Amperometry	Same
Enzyme	Glucose Oxidase (Aspergillus niger)	Same
Control solution	Contrex Plus III control solution (Low, L1, L2)	Same
Test Strip	GAL-1C Test Strip	Same (except for GAL-1E and GAL-1E Multi trade names)
Calibration Coding	Autocoding	Same
Power supply	One (1) CR 2032 3.0V coin cell battery	Same
Physical size	56L x 63H x 13H (mm)	82.5L x 47.3W x 13.3H (mm)
Weight	29g (without battery)	37g (without battery)
LCD display	Orientation: horizontal Size: 29H x 39W (mm)	Orientation: Vertical Size: 39H x 29W (mm)
Strip ejection button	No	Yes
Memory	300 results	Same
Test range	20 – 600 mg/dL	Same
Hematocrit range	30 – 55%	Same
Sample type	Fresh capillary whole blood	Same
Sample sites	Fingertip, forearm, and palm	Same
Sample volume	0.8 μL	Same
Sample test time	6 seconds	Same

K. Standard/Guidance Document Referenced (if applicable):

1. ISO 15197; 2003, In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus.

2. CLSI - EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

3. IEC – 60601 – 1- 2; 2001, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility-Requirements and Tests

4. IEC – 61000-3-2; 2005, Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current ≤ 16A per phase)

5. IEC – 61000-3-3; 2005, Electrical equipment for measurement, control and laboratory use-EMC requirements – Part 1: General requirements

6. IEC – 61326 – 1; 2005, Electrical equipment for measurement, control and laboratory use-EMC requirements – Part 1: General requirements

7. IEC – 61326 – 2-6; 2005, Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment

8. IEC – 61010 – 1; 2010, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements

9. IEC/EN – 61010-2-101; 2009, Safety requirements for electrical equipment for measurement, control and laboratory use- Part2 – 101: Particular requirements for in vitro diagnostic (IVD) medical equipment

10. IEC – 60601-1; 1995, Medical Electrical Equipment – Part 1: General Requirements for Safety

11. CEN/EN 55011; 2007, Industrial, scientific and medical (ISM) radio-frequency Equipment, Electromagnetic disturbance characteristics. Limits and methods of measurement

L. Test Principle:

The GAL-1E and GAL-1E Multi Blood Glucose Monitoring System Blood Glucose Monitoring System uses glucose oxidase enzyme chemistry as the standard dry reagent assay for glucose in whole blood. This enzyme assay, with a redox chemical "mediator" reaction, is used to generate an electrical current proportional to the glucose concentration in the blood sample. The system is designed as an amperometric measurement device using current generated for the redox reaction as the measureable response.

M. Performance Characteristics (if/when applicable):

The GAL-1E and GAL-1E Multi Blood Glucose Monitoring Systems are identical meters. The differences between these meters are that they are marketed under

different trade names and also differ in their intended use population (single-patient use vs. multiple-patient use.

1. Analytical performance:

   a. *Precision/Reproducibility:*
   Precision previously reviewed in the GAL-1C submission (k102816).

   b. *Linearity/assay reportable range:*

   The linearity study was designed following CLSI EP6-A guideline. Venous whole blood was used for this study. Eight target glucose concentrations were prepared by either spiking glucose stock solution into the sample or by allowing the sample to undergo glycolysis to achieve the following levels:

Glucose level	Glucose range (mg/dL)
1	15 – 20
2	35 – 60
3	70 – 85
4	115 – 150
5	195 – 230
6	290 – 330
7	400 – 450
8	600 - 620

   A total of 40 strips per lot (3 lots total) were used at each glucose concentration using 10 GAL-1E meters. All samples were also tested on a YSI analyzer to generate the expected values. The observed values were plotted against an average of the expected values and an appropriate line fitted by standard linear regression was generated with results summarized below:

Strip Lot	Slope	Intercept	R^2
1	1.0148	-1.939	0.9990
2	1.0359	-3.9638	0.9988
3	1.0115	-2.8838	0.9986

   The study provided supports the sponsor's claimed measurement range for glucose is 20 - 600 mg/dL.

   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

   Traceability: GAL-1E Glucose Monitoring System is traceable to NIST reference material using NERL standards.

Test Strip Stability:

The GAL-1E test strips are identical to the GAL-1C test strips and are stored in the identical vial. Open and Closed vial stability previously reviewed in the GAL-1C submission (k102816). The Shelf life is 17 months when stored at 41 - 86ºF and the open vial stability is 3 months after first opening.

Control Solution Stability:

The Contrex Plus III control solution open and closed vial stabilities previously reviewed in the GAL-1C submission (k102816). The Shelf life is 18 months when stored at 15 - 30ºC and the open vial stability is 3 months after first opening.

d. Detection limit:

See linearity study above.

e. Analytical specificity:

Potential endogeneous and exogenous interference previously reviewed in the GAL-1C submission (k102816).

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

System accuracy study:

This study was conducted using samples collected from 158 participants. Samples containing <50 mg/dL of glucose were allowed to glycolyze and to obtain sample values >450 mg/dL, samples were spiked with a glucose stock solution. The range of samples tested was 35 mg/dL to 506 mg/dL (according to YSI) collected by fingertip. Nine (9) GAL-1E meters and three (3) lots of GAL-1E test strips were used. Results obtained by the trained professional were compared to YSI. The glucose meter measurements obtained using the GAL-1E BGMS were compared to the YSI method for fingerstick, palm, and forearm samples. The results are shown in the following tables:

Regression analysis of samples is summarized below:

Linear Regression: GAL-1E glucose meter vs. YSI reference method				
Sample site	Sample number	Slope	Intercept	R^2
Fingertip	158	0.9986	-0.2554	0.9917
Palm	144	0.9859	-0.6284	0.9899
Forearm	144	0.9833	1.7152	0.9889

Fingertip: glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
19/26 (73%)	24/26 (92%)	26/26 (100%)

Fingertip: System accuracy results for glucose concentrations ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
80/132 (61%)	122/132 (92%)	132/132 (100%)	132/132 (100%)

Palm: System accuracy results for glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
10/18 (56%)	17/18 (94%)	18/18 (100%)

Palm: System accuracy results for glucose concentration ≥75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
51/126 (64%)	112/126 (89%)	126/126 (100%)	126/126 (100%)

Forearm: System accuracy results for glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
11/18 (61%)	18/18 (100%)	18/18 (100%)

Forearm: System accuracy results for glucose concentrations ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
80/126 (64%)	114/126 (91%)	126/126 (100%)	126/126 (100%)

System Accuracy for lay-users was previously evaluated with the GAL-1C (k102816) submission.

b. Matrix comparison:

None. Only capillary whole blood samples are acceptable matrix.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Expected values/Reference range: Time of day	Range, Non-diabetes
Before meals	Less than 100 mg/dL
After meals	Less than 140 mg/dL

The sponsor references: American Diabetes Association. Standards of Medical Care in Diabetes, Diabetes Care. 2010; 33:S11-S61.

N. Instrument Name:

The GAL-1E and GAL-1E Multi Blood Glucose Meters

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and requires a sample volume of 0.8 uL.

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes _____ or No __X_____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes _____ or No ___X____

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes ___X_____ or No _____

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   The glucose test is intended to be used with capillary whole blood from the finger, palm, and forearm only. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   There is no calibration required for the GAL-1E and GAL-1E Multi meters by the user. The meter is plasma-calibrated.

6. Quality Control:

   Glucose control solutions at three different concentrations can be run with this device. The meter has an algorithm to automatically recognize the control solutions to prevent control results from being stored in the internal memory as patient result. Recommendations on when to test the control materials are provided in the labeling. The control solution readings are not included in the average of the patient results. An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1. Altitude Study:
   Previously reviewed in the GAL-1C submission (k102816) and supports the altitude claim of up to 10,335 feet.

2. Hematocrit Study:
   Previously reviewed in the GAL-1C submission (k102816) and found acceptable performance of the GAL-1C blood glucose monitoring system at HCT 30-55%.

3. Temperature and Relative Humidity Study:
   Previously reviewed in the GAL-1C submission (k102816). The study results met pre-determined acceptance criteria and support the temperature and humidity claims of 10-40°C and 20-85% RH.

4. EMC Electromagnetic Compatibility and Electrical Safety verification testing of the GAL-1E Blood Glucose Monitoring System was performed following the requirements of ISO 15197:2003 (E).

5. Sample volume study:
   Previously reviewed in the GAL-1C submission (k102816) and found acceptable performance using sample volumes ≥0.8µl.

6. Infection Control Studies:

   GAL-1E Blood Glucose Meter

   The device system is intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter and lancing device by an outside commercial testing demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Dispatch Hospital Cleaner Disinfectant Towels with Bleach (EPA Registration # 56392-8). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter and lancing device after 1,825 cleanings and 1,825 disinfection steps with the Dispatch Hospital Cleaner Disinfectant Towels with Bleach wipes. The robustness studies were designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

   GAL-1E Multi Blood Glucose Meter

   The device system is intended for use in multiple patients with use of a single use, auto-disabling lancet device. Disinfection efficacy studies were performed on the materials comprising the meter and lancing device by an outside commercial testing demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Dispatch Hospital Cleaner Disinfectant Towels with Bleach (EPA Registration # 56392-8). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter and lancing device after 10,950 cleanings and 10,950 disinfection steps with the Dispatch Hospital Cleaner Disinfectant Towels with Bleach wipes. The robustness studies were designed to simulate 3 years of multiple-patient use Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7. Readability: The readability of the labeling (user guides, test strip package insert and control solution package insert) was previously reviewed the GAL-1C (k102816) submission using a Flesch-Kincaid analysis and were found to be written at the 8th grade level. The labeling of the candidate meters (GAL-1E and GAL-1E multi) are identical to the GAL-1C meter.

8. LO/HI Detection:

The low and high detection limits were evaluated to ensure that glucose values <20 mg/dL are reported by the meter as "LO" and values >600 mg/dL are reported as "HI".

9. Drop Test:
   In this study, twenty five (25) GAL-1E meters were dropped from a height of 1 meter onto a concrete floor. Each meter was dropped (without a test strip) on all 6 sides, two times per side, and additionally (with a test strip), dropped on the strip holder side two times. All meters did not break throughout the drop test study, maintained functionality after being dropped, and provided accurate glucose control readings (Contrex Plus III level 1) 85 – 127 mg/dL.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.