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

A. 510(k) Number:

k101037

B. Purpose for Submission:

New device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative amperometric whole blood glucose dehydrogenase (GDH-FAD)

E. Applicant:

EPS Bio Technology Corp.

F. Proprietary and Established Names:

EG V1(BL) Self Monitoring Glucose Test System, EG V1 Pro Self Monitoring Glucose Test System, EG V1 Quality Control solutions

G. Regulatory Information:

Device	Regulation	Classification	Product Code
EG V1(BL) Self Monitoring Glucose Test System	21 CFR§ 862.1345, Glucose Test System	II	LFR, NBW (over the counter)
EG V1 PRO Self Monitoring Blood Glucose Test System	21 CFR§ 862.1345, Glucose Test System	II	LFR
EG Glucose Control Solution	21 CFR§ 862.1660, Quality Control Material (assayed and unassayed)	I, reserved	JJX

4. Panel:

(75) Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   See Indications for Use below.

2. Indication(s) for use:

   The **EG V1 Pro Self Monitoring Blood Glucose Test System** is intended for the quantitative measurement of glucose in venous whole blood or fresh capillary whole blood from the fingertip. Testing is done outside the body (In Vitro diagnostic use). It is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use lancing devices. The system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus.

   The system consists of the **EG V1 Pro meter** and the **EG Pro Test Strips**. The EG V1 Pro meter only is used with the EG Pro Test Strips to quantitatively measure glucose in venous whole blood or fresh capillary whole blood from the fingertip.

   The **EG V1 (BL) Self Monitoring Blood Glucose Test System** is intended for the quantiatative measurement of glucose in fresh capillary whole blood from the fingertip, palm or forearm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. The system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus. Alternative site testing can only be used during steady-state blood glucose conditions.

   The system consists of the **EG V1 (BL) meter** and the **EG V1 Test Strips**. The EG V1 (BL) meter only is used with the EG V1 Test Strips to quantitatively measure glucose in venous whole blood or fresh capillary whole blood from the fingertip, palm, or forearm.

   The **EG Glucose Control Solution**
   For use with the EG V1 Pro and EG V1(BL) Blood Glucose Self Monitoring Systems as a quality control check to verify the accuracy of blood glucose test results.

3. Special conditions for use statement(s):
   a. For Over-the-Counter use.
   b. Not for use with neonates.
   c. Not for use in patients experiencing dehydration, frequent urination, low blood pressure, shock, hyperosmolar hyperglycemic nonketotic coma (HHNKC).
   d. Alternative site testing (AST) can only be used during steady-state blood glucose conditions. AST should only be performed under the following conditions:
      - Testing before a meal.
      - In a fasting state.

- Two hours or more after a meal.
- Two hours or more after insulin dosing.
- Two hours after physical activity.

e. Alternative site testing (AST) should not be used to calibrate continuous glucose monitors (CGMs) nor for use in insulin dose calculations.
f. Multiple user devices (EG V1 PRO) must be disinfected between users following labeling recommendations.
g. Multiple user practice settings are to use disposable, single use lancing devices with the meters.

4. Special instrument requirements:

The EG V1(BL) Meter and EG Glucose Test Strips

EG V1 PRO Meter and EG V1 Pro Glucose Test Strips

Disposable, single use lancet devices are used with the EG V1 PRO Self-Monitoring Blood Glucose System.

I. Device Description:

The EG V1(BL) Self-Monitoring Blood Glucose System consists of the EG V1 Blood Glucose Meter, User's Manual, Quick Guide, EG Glucose Test Strips, lancing device, and EG level 2 Control Solution. The EG V1(BL) Blood Glucose Meter is a "no code" meter and can be operated from 10-40° C and 40-85% RH. The device can be used to measure whole blood glucose in venous or fresh capillary samples from the forearm, palm or finger.

The EG V1 PRO Self-Monitoring Blood Glucose System consists of the EG V1 Pro meter and EG V1 Pro Glucose Test Strips, User's Manual, and Quick Guide. The EG V1 Pro Blood Glucose Meter is a "no code" meter and can be operated from 10-40° C and 40-85% RH. The device can be used to measure whole blood glucose in venous or fresh capillary samples from the finger.

The EG Glucose Control Solutions are aqueous based materials at 2 glucose concentrations. Level 2: medium level contains 0.12% concentrations of glucose (approximately 120 mg/dL) and Level 3: high level contains 0.35% concentrations of glucose (approximately 350 mg/dL). Level 2 is included in the start-up kit for the EG V1 Blood Glucose Monitoring System.

The differences between the EG V1(BL) Self-Monitoring Blood Glucose System and the EG V1 PRO Self-Monitoring Blood Glucose System are labeling, which includes disinfection instructions for using the device in multiple patient use settings, and lancing devices. The EG V1 PRO Self-Monitoring Blood Glucose System uses the disposable single use lancing device and the EG V1(BL) Self-Monitoring Blood Glucose System uses the adjustable height lancing device. The EG Control 3 is purchased separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Bayer Ascensia Contour Blood Glucose Meter, Model 7151; Reagent Strip, Model 7080

2. Predicate 510(k) number(s):

   k062058

3. Comparison with predicate:

Similarities		
Item	Device EG V1 (BL)	Predicate
Intended use/indications for use	Same	Is used for the measurement of glucose in whole blood. Is an over-the-counter (OTC) device used by persons with diabetes and by healthcare professionals in home settings and in healthcare facilities. Capillary samples may be drawn from the fingertip, palm, and forearm. The frequent monitoring of blood glucose is an adjunct to the care of persons with diabetes.
Detection method	Same	Amperometry
Enzyme	Same	Glucose Dehydrogenase (FAD)
Sample volume	Same	> 0.6 uL
Temperature range	Same	10°-40°C
Memory capability	Same	480 tests with date and Time
Hematocrit range	Same	20-60%
Power	Same	3V CR2032 batteries

Item	Device – EG V1 Pro	Predicate
Intended use/indications for use	Same	Is used for the measurement of glucose in whole blood. Is an over-the-counter (OTC) device used by persons with diabetes and by healthcare professionals in home settings and in healthcare facilities. Capillary samples may be drawn from the fingertip, palm, and forearm. The frequent monitoring of blood glucose is an adjunct to the care of persons with diabetes.
Detection method	Same	Amperometry
Enzyme	Same	Glucose Dehydrogenase

Item	Device – EG V1 Pro	Predicate
		(FAD)
Sample volume	Same	> 0.6 uL
Temperature range	Same	10°-40°C
Memory capability	Same	480 tests with date and Time
Hematocrit range	Same	20-60%
Power	Same	3V CR2032 batteries

Differences		
Item	Device EG V1 (BL)	Predicate
Test range	20-600 mg/dL	10-600 mg/dL
Anatomical Sites	Venous sample and Capillary samples from the fingertip, palm, forearm,	Capillary samples from the fingertip, palm, forearm, abdomen and thigh
Test time	5 seconds	8 seconds
Size L x W x H (inch)	3.5”x 2.1”x 0.97”	2.8”x 2.35”x 0.77”
Weight	2.05 oz (without batteries)	2.0 oz (without batteries)
User settings	Single user only. Not for use in multiple user settings	Professional and home use
Cleaning/disinfection studies	See section P.1	No studies performed.
Intended use population	Does not include neonates, or multiple users	Includes neonates, single, and multiple users

Differences		
Item	Device EG V1 Pro	Predicate
Test range	20-600 mg/dL	10-600 mg/dL
Anatomical Sites	Venous sample and Capillary samples from the fingertip, palm, forearm,	Capillary samples from the fingertip, palm, forearm, abdomen and thigh
Test time	5 seconds	8 seconds
Size L x W x H (inch)	3.5”x 2.1”x 0.97”	2.8”x 2.35”x 0.77”
Weight	2.05 oz (without batteries)	2.0 oz (without batteries)
User settings	Multiple users	Professional and home use
Intended use population	Does not include use on neonates	Includes use on neonates

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

ISO 15197:2003, *In Vitro* Diagnostic Test Systems—Requirements for Blood Glucose Test Systems for Self Managing Diabetes Mellitus.

ISO 14971: 2007, Application of Risk Management to Medical Devices

IEC/EN 61601-1-2, (Second Edition, 2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - - Requirements and Tests. (General)

CLSI EP5-A: Precision Performance for Quantitative Measurements

CLSI EP7-A: Interference Testing in Clinical Chemistry

FDA Guidance Document: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

L. Test Principle:

The EG V1(BL) Self-Monitoring Blood Glucose System and EG V1 PRO Self-Monitoring Blood Glucose System employ a disposable dry reagent strip technology, based on the glucose dehydrogenase method for glucose determination. Each test strip features an electrode containing the glucose dehydrogenase in the presence of the coenzyme Flavin Adenine Dinucleotide (FAD). A blood sample is applied to the blood collection area at the tip of the strip and is automatically drawn into the reaction zone, where the FAD-binding glucose dehydrogenase catalyzes the dehydrogenation of glucose to produce gluconolactone. During the reaction, a mediator transfers electrons to the electrode surface and generates a current. The amount of the current is proportional to the amount of glucose present in the blood sample the glucose concentration is measured by the EG V1(BL) Glucose Meter and displayed on the screen after 5 seconds.

M. Performance Characteristics (if/when applicable):

1. Analytical performance: **The EG V1(BL) and EG V1 Pro are the same meters and test strips, however, they have separate names because of the different indications for use.**

   a. Precision/Reproducibility:

   The repeatability study was performed by one operator with two test strip lots and 10 meters to analyze the normal control solution and six venous blood samples spiked to concentrations that covered the measuring range of the device. Each blood sample and control was tested 10 times (N=200).The final glucose concentrations for the blood samples were confirmed by YSI. The blood samples had hematocrit levels of 20%-60%. The data is summarized below:

Repeatability

Range (mg/dL)	N	EG V1(BL) SMBG system		
		Mean (mg/dL)	SD	CV%
20-50 mg/dL	200	40.7	2.6	6.5

51-110 mg/dL	200	108.5	3.5	3.2
111-150 mg/dL	200	137.0	4.5	3.3
151-250 mg/dL	200	223.5	6.4	2.9
251-400 mg/dL	200	399.8	11.0	2.8
401-600 mg/dL	200	512.1	13.9	2.7
Control solution	200	118.2	3.3	2.8

Intermediate precision studies were performed by two operators with two test strip lots and 10 meters analyzing 3 glucose control solutions for 10 days (N=400).

Intermediate Precision

Control solution	N	Mean (mg/dL)	SD	CV%
1	400	41.8	3.12	3.12
2	400	120.7	3.09	2.56
3	400	349.8	7.24	2.07

b. *Linearity/assay reportable range:*
Linearity study was performed using 7 venous blood samples spiked with dextrose that covered the range from 20.2-599 mg/dL. Glucose concentrations were confirmed by the YSI. One operator performed the study in singlicate on 3 test strip lots on one of 5 meter selected at random over 10 days (N=210). Results are below:

Strip Lot	Slope	Intercept	R^2	Syx
051101701	0.9785	0.8308	0.9974	8.167
051101702	0.9826	0.9001	0.9977	7.607
051101703	0.9815	0.7231	0.9969	8.946
Pooled	0.9809	0.8180	0.9973	8.245

The measurement range of the EG V1 Pro and EG V1(BL) Blood Glucose Meter is 20-600 mg/dL.

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

EG Controls

EG Glucose Control Solutions: Controls are traceable to the YSI and NIST Reference material 965b. Value assignment was performed with 10 meters, and 2 lots of test strips for 10 days. The mean, 2 standard deviations and CV are calculated for each new lot of control material. The control range for each strip lot must be within mean ± 15% and CV ≤ 6%. The target means for Controls 2 and 3 are 120 mg/dL and 350 mg/dL, respectively.

Open vial control stability was tested at three control levels on two lots. The protocol was carried out at the same temperatures as the open vial test strip studies. Controls

were tested weekly. Based on these studies, open vial stability is 90 days when stored at 2-30°C. Unopened control solutions were tested under identical conditions as the closed test strip studies. Unopened control solutions have a 12 month shelf life.

EG V1 Pro and EG V1 (BL) Glucose Test Strips

Real time stability was performed to assess the shelf-life and open-vial stability of the test strips. Stability studies protocol and acceptance criteria were provided and found to be adequate. The sponsor claimed that the unopened test strips have a 12 month shelf-life and are stable for 3 months after first use when stored at 2-30°C. This information is provided in the labeling of the test strips and control materials.

Open vial test strip stability was evaluated in real-time and accelerated studies using 2 lots of test strips and 3 whole blood concentrations, 50 ± 5 mg/dL, 100 ± 10 mg/dL and 400 ± 10 mg/dL. Blood sample results on the meters were compared to the YSI. Strips in the real time study were stored at 4±2°C and 23±2°C and 32±2°C and tested weekly with controls and whole blood. Based on these studies, open vial stability is 90 days when stored at 2-30°C. Studies to evaluate the closed vial stability were conducted at the same temperatures and sample range. Closed vial stability is one year when stored 2-30°C.

d. Detection limit:

The reportable range is 20 to 600 mg/dL based on linearity/reportable range studies above (section M.1.b.).

e. Analytical specificity:

Interference studies for endogenous, and exogenous, studies were conducted on 5 EG V1 meters, and two lots of test strips using venous blood samples with three glucose concentrations of approximately 80mg/dL, 120mg/dL, and 500 mg/dL. Interference was evaluated in 24 common endogenous and exogenous potential interferents within the therapeutic ranges and at above therapeutic or toxic ranges. Significant interference is defined as a bias ≥ 10 % from the control group as measured on YSI..

The sponsor claims no significant interference (≤ 10% difference) for the substances and concentrations shown in the table below:

Interferent	Concentration tested up to (mg/dL)
Gentisic Acid	6
Ascorbic Acid	4
Ibuprophen	50
Methyldopa	2
Sodium Salicylate	50
Tetracycline	1.5

Tolbutamide	100
Galactose	20
Maltose	20
Manose	10
Sucrose	50
Xylitol	200
Glipizide	8
Bilirubin	25
Cholesterol	500
Creatinine	30
Triglycerides	1000
Fructose	30

Interference was observed with the substances below at the concentrations listed.

Interferent	**Interference observed at (mg/dL)**
Acetaminophen	8
Dopamine	5.2
L-Dopa	4
Xylose	8
Uric Acid	15.9

Hematocrit Study:
The effect of different hematocrit levels on the accuracy of the device was evaluated on the EG V1(BL) Blood Glucose Monitoring System with 5 meters and two test strip lots. Blood samples at 5 hematocrit levels from 20% to 60% (20, 30, 40, 50, 60) were adjusted to 4 concentrations of glucose of approximately 50, 150, 200, and 550 mg/dL. N=20 for each hematocrit level at each glucose concentration. Glucose concentrations were compared to YSI. No significant interference from hematocrit was defined as bias within ± 15%. Hematocrit 20%-60% does not significantly interfere with glucose concentrations between 50-550 mg/dL.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

The method comparison study was conducted at three clinical sites using three EG V1(BL) meters, and three lots of test strips on paired venous whole blood and fingerstick capillary blood (n=153). Venous blood samples were collected in lithium heparin. Fingerstick samples were collected with single use, disposable lancets by lay users and then by healthcare professionals (HCP) who also drew a venous blood sample. Labeling was provided only in English and users followed it to perform

testing. Distribution of glucose concentrations across the measuring range was: 73 samples between 58.5-120 mg/dL, 52 samples between 121-190 mg/dL and 28 samples between 191-433.5 mg/dL. An additional 8 samples were altered to meet the extreme high and low ends of the measuring range (N=161, range 36.5-570.5 mg/dL). All results were compared to the YSI. Hematocrit levels of the samples ranged from 25.9-59.9%. The meters were cleaned between each patient use following the protocol described in the labeling with the recommended disinfectant wipes. The studies met ISO 15197 accuracy criteria, e.g., 95% of glucose results < 75 mg/dL were within ± 15 mg/dL, and for samples ≥ 75 mg/dL, 95% of results were within ± 20% of the reference method. Results are summarized below:

Lay User Fingerstick and Healthcare Professional Fingerstick vs YSI

	Lay User	HCP
Slope	1.0100	1.0190
Intercept	-0.9679	-2.9299
r^2	0.9696	0.9823

Lay User Fingerstick vs YSI ≤ 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
14/19 (73.68%)	19/19 (100%)	19/19 (100%)

Lay User Fingerstick vs YSI > 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
83/134 (61.94%)	115/134 (85.82%)	129/134 (96.27%)	131/134 (97.76%)

Healthcare Professional Fingerstick vs YSI ≤ 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
16/19 (84.21%)	17/19 (89.47%)	19/19 (100%)

Healthcare Professional Fingerstick vs YSI > 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
102/134 (76.12%)	125/134 (93.28%)	129/134 (96.27%)	132/134 (98.51%)

Healthcare Professional Venous Blood vs YSI

The regression for all venous blood samples (n=161) is: y = 0.9874x + 1.5835, r^2=0.9744

Healthcare Professional Venous Blood vs YSI ≤ 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
16/22 (72.73%)	22/22 (100%)	22/22 (100%)

Healthcare Professional Venous Blood vs YSI > 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
81/139 (58.27%)	111/139 (79.86%)	127/139 (91.37%)	135/139 (97.12%)

Alternative site testing for the thenar, hypothenar and arm was performed by lay users, in a glucose steady state, at three sites. Labeling was provided in English to the participants and the lay users obtained their own samples (n=153) and analyzed them on one EG V1(BL) meter. 3 lots of test strips were used throughout the course of the study. A health care professional also obtained samples from each testing site of the participants and analyzed the samples on the same EG V1(BL) meter. All samples were natural samples with values ranging from 51 mg/dL – 447 mg/dL. Accuracy across the measuring range was evaluated using Deming regression and ISO 15197 criteria. Results are summarized below. Labeling states that alternative site testing should not be used when the user suspects their blood glucose level is low, if they are not aware of symptoms of hypoglycemia, the site results do not agree with the way the user feels, after a meal or exercise, during illness or times of stress, or to calibrate continuous glucose monitors or for insulin dosing calculations.

Lay User Thenar and Healthcare Professional Thenar vs YSI

	Lay User	HCP
Slope	0.9688	1.0101
Intercept	4.8241	-0.6506
r^2	0.9481	0.9719

Lay User Thenar vs YSI ≤ 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
12/19 (63.16%)	17/19 (89.47%)	19/19 (100%)

Lay User Thenar vs YSI > 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
63/134 (47.01%)	99/134 (73.88%)	121/134 (90.30%)	129/134(96.27%)

Healthcare Professional Thenar vs YSI ≤ 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
16/19 (84.21%)	19/19 (100%)	19/19 (100%)

Healthcare Professional Thenar vs YSI > 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
76/134 (56.72%)	112/134 (83.58%)	128/134 (95.52%)	131/134 (97.76%)

Lay User Hypothenar and Healthcare Professional Hypothenar vs YSI

	Lay User	HCP
Slope	1.0896	1.0537
Intercept	-11.7596	-7.1471
r^2	0.9584	0.9673

Lay User Hypothenar vs YSI ≤ 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
9/19 (47.37%)	16/19 (84.21%)	18/19 (95%)

Lay User Hypothenar vs YSI > 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
66/134 (49.25%)	95/134 (70.90)	113/134 (84.33%)	129/134 (96.27%)

Healthcare Professional Hypothenar vs YSI ≤ 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
15/19 (78.95%)	17/19 (89.74%)	18/19 (95%)

Healthcare Professional Hypothenar vs YSI > 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
82/134 (61.19%)	107/134 (79.85%)	121/134 (90.30%)	130/134 (97.01%)

Lay User Arm and Healthcare Professional Arm vs YSI

	Lay User	HCP
Slope	1.0263	1.0282
Intercept	-4.6425	-3.9814
r^2	0.9503	0.9650

Lay User Arm vs YSI ≤ 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
8/19 (42.11%)	14/19 (73.68%)	19/19 (100%)

Lay User Arm vs YSI > 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
59/134 (44.03%)	97/134 (72.39%)	112/134 (87.31%)	128/134 (95.52%)

Healthcare Professional Arm vs YSI ≤ 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
12/19 (42.11%)	18/19 (94.74%)	19/19 (100%)

Healthcare Professional Arm vs YSI > 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
81/134 (60.45%)	106/134 (79.10%)	117/134 (87.31%)	128/134 (95.52%)

b. Matrix comparison:

Matrix comparison studies were performed with venous whole blood collected in sodium heparin, lithium heparin, EDTA, and sodium fluoride. 5 meters and 2 test

strip lots were used for the study. Blood samples were adjusted to concentrations of 40-60 mg/dL, 110-130 mg/dL, 340-360 mg/dL and 490-510 mg/dL as determined by YSI. Each preservative type was run in duplicate for each strip lot on each meter for each glucose concentration (N=320). Bias needed to be within ± 10% of the YSI value. Based on this study, sodium heparin, lithium heparin, and EDTA are appropriate sample preservatives. Sodium fluoride is not an appropriate preservative for the EG V1(BL) and EG V1 Pro Blood Glucose Monitoring Systems. Results are summarized in the table below. See section M.2.a. for the comparison between venous whole blood and capillary samples.

Specimen Type	Anticoagulant	Slope	Y-intercept	R2
Venous Blood	Na Heparin	1.0309	-13.382	0.9919
	Li Heparin	1.0269	-12.394	0.9944
	EDTA	0.9631	+7.360	0.9943
Capillary Blood	Na Heparin	0.9908	-6.770	0.9949
	Li Heparin	1.0254	10.623	0.9935
	EDTA	1.0225	0.4994	0.9972

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):

   Not applicable

4. Clinical cut-off:

   Not applicable.

5. Expected values/Reference range:

   Expected blood glucose results for non-pregnant people without diabetes were cited from literature[1] and presented in the labeling as follows:

   Fasting: 70-130 mg/dL,
   2 hours after meal: < 180 mg/dL

[1]American Diabetes Association: Standards of medical Care in Diabetes—Table 8, Diabetes Care, 2008, S18.

N. Instrument Name:

EG V1 Pro Blood Glucose, Meter and EG V1(BL) Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and requires a sample volume of 0.6 micL.

   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:

   The EG V1 meter is a no code device. Reaction intensities of new test strip lots must meet the manufacturer's no code criteria for use with these meters. Validation of new strip lots is confirmed by comparison to the YSI across the measuring range of the device.

6. Quality Control:

   Glucose control solutions at two 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 control solutions 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. The device is intended for single-patient (EG V1) or healthcare professional use (EG V1 Pro). Disinfection studies were performed on the EG V1 Pro meter and lancet device by an outside commercial testing service to determine the robustness of the meter and lancing device to the recommended cleaning and disinfection protocol, and its effectiveness in preventing the spread of bloodborne pathogens, particularly hepatitis B virus (HBV). PDI® SANI-CLOTH® Germicidal disposable wipes (EPA Reg. No: 9480-4) were validated, demonstrating complete inactivation of live virus for use with the meter and lancing device. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter and lancing device after 14,700 disinfection and 7,300 cleaning cycles designed to simulate 3 years of healthcare professional use and 4 years of use by lay users.

2. Insufficient sample studies were performed at volumes ± 25% of the recommended volume (0.6 mcL) on 5 meters and two test strip lots. Each sample was tested in duplicate per strip lot. 7 glucose concentrations were tested ranging from approximately 50-500 mg/dL, as determined by the YSI. Appropriate sample volume was determined if the meter results matched the YSI results. A blood volume ≥ 0.5 mcL met the criteria.

3. Altitude studies were conducted up to 10,000 ft (3,150 meters) using 5 venous blood samples covering the measuring range of the device. Two lots of test strips and 10 meters were evaluated. Results were compared to the YSI. Meter performance was not significantly (significant interference is defined as > ± 10%) affected up to 10,000 ft.

4. The effect of relative humidity was evaluated from 40 ± 5% to 85 ± 5% using 2 meters, 2 strip lots, measuring 3 blood samples in quintuplicate per meter. Blood samples ranged from 20-70 mg/dL, 96-144 mg/dL and 280-600 mg/dL. Meter values needed to be within the YSI ≤ 10%. Results met the acceptance criteria for 35± 5% to 85 ± 5%. The testing supported the claimed shelf life of 12 months when stored at relative humidity of 40-85%.The EG V1 Blood Glucose Meter normalizes the sample temperature (in vitro) to the in vivo temperature (37°C). To validate and verify performance across several temperature ranges, 5 meters and 2 strip lots were evaluated at 15 temperatures ranging from 11 ± 1°C to 39 ± 1°C using 3 whole blood concentrations spanning the measuring range and comparing the values to the YSI ±10%. Whole blood concentrations were 100 ± 5 mg/dL, 250 ± 5 mg/dL, 450 ± 5 mg/dL. Relative humidity was 49-56%. There were no significant differences in glucose concentrations across the temperature and humidity ranges tested.

5. Open-vial-in-use test strip studies were performed at the combined extremes of 10±2°C (46.4-56.3°F) RH: 40%, 10±2°C RH:85%, 40±2°C (100.4-107.6°F) RH:40%, and 40±2°C RH:85% with 5 venous blood samples with concentrations across the measuring range and compared to the YSI. The study protocol, data and acceptance criteria were provided and found to be adequate.

6. A usability study was performed to assess the readability of the labeling by recruiting 151 lay users (aged 18-70 yrs old) who were provided with the test kit containing labeling in English for the US market. Participants varied in age, education, country of origin, and were about evenly divided between men and women. These lay users also completed a questionnaire to indicate whether the device is easy to use and the Instructions for use were written in a way that makes it easy to use. The majority of the users responded that the device is very easy to use.

7. Flesch-Kincaid readability assessment was conducted and the results showed that the labeling (User Guide, test strip package insert and control solution package insert) were written at the 8th grade level.

8. EMC testing was evaluated and certified by Bureau Veritas Consumer Products Services (H.K.) Ltd., Taoyuan Branch and a letter of attestation was issued to EPS Bio Technology Corp. on March 10, 2010.

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.