K101037

MAY 2 3 2011

510(k) SUMMARY for
EG V1 Pro Self Monitoring Glucose Test System

A. Submitter's information

Company: EPS Bio Technology Corp.
Address: No. 8, R&D RD. III, Hsinchu Science Park Hsinchu City, Taiwan, R.O.C.
Contact Name: Mr. Y.C. Lei, General Manager
Phone: 886-3-6686868
Fax: 886-3-6686866

B. Measured:

Glucose

C. Type of Test:

Quantitative; electrochemical biosensor

D. Proprietary and Established Names:

EG V1 Pro Self-Monitoring Blood Glucose Test System

E. Common or Usual Name:

Glucose Test System

F. Regulatory Information:

1. Regulation section:
   21 CFR 862.1345, Glucose Test System
   21 CFR 862.1660, Quality control materials (assayed and unassayed)

2. Classification:
   Class II
   Class I, reserved

3. Product code:
   NBW, System Test, Blood Glucose, Over the Counter
   LFR, Glucose Dehydrogenase, Glucose
   JJX, Single (Specified) Controls (assayed and Unassayed)

4. Panel:
   Chemistry 75

G. 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 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 fingertip.
The **EG Glucose Control Solution**
For use with the EG V1 Pro Blood Glucose Self Monitoring System as a quality control check to verify the accuracy of blood glucose test results.

H. Device Description:

The EG V1 Pro Self-Monitoring Blood Glucose System consists of the EG V1 Pro Blood Glucose Meter, EG Pro Glucose Test Strips, single-use Lancing Device and EG Level 2 Control Solution. (Please refer to the IFU for the product picture)

I. Substantial Equivalence Information:

1. Predicate device name(s):
ASCENSIA CONTOUR BLOOD GLUCOSE METER, MODEL 7151; REAGENT STRIP, MODEL 7080

2. Device Company
BAYER HEALTHCARE

3. Predicate 510(k) number(s):
k062058

4. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection method	Amperometry	Amperometry
Enzyme	Glucose Dehydrogenase (FAD)	Glucose Dehydrogenase (FAD)
Sample volume	$\geq$ 0.6 uL	$\geq$ 0.6 uL
Temperature range	10-40^{0}C	10-40^{0}C
Memory capability	480 tests with date and time	480 tests with date and time
Hematocrit range	20-60%	20-60%
Power	3V CR2032 batteries	3V CR2032 batteries

Differences		
Item	Device	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)

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

1. ISO 15197:2003, In Vitro Diagnostic Test Systems – Requirements for Blood Glucose Monitoring Test Systems for Self Managing Diabetes Mellitus.
2. ISO 14971:2007, Medical Devices – Application of Risk Management to Medical Devices.
3. EN 13640:2002, Stability Testing of In Vitro Diagnostic Reagents.
4. IEC 60601-1-2:2004, Medical electrical equipment - Part 1: General requirement for safety; Electromagnetic compatibility -Requirements and tests.
5. IEC 61010-2-101:2002, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment.
6. IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Safety.
7. CLSI EP7-2A:2005, Interference Testing in Clinical Chemistry.

K. Test Principle:

The EG V1 Pro Self-Monitoring Blood Glucose System employs a disposable dry reagent strip technology, using glucose dehydrogenase method to quantify glucose. 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 glucose to dehydrogenate and 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 calculated in the EG V1 Pro Glucose Meter and displayed on the screen after 5 seconds.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within-run Precision – The testing was used by venous blood, which was stored in the heparin blood collection tube. Glucose was glucolyzed/spiked to the blood to prepare 6 different levels of glucose concentration: 20-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, 251-400 mg/dL, and 401~600 mg/dL. For each testing range, 10 meters, 10 pcs of test strips for each meter, and 2 lots of test strips were used.
(N=10 Meters x10 tests x 2 lots =200)

Range (mg/dL)	N	EG V1 SMBG system		
		Mean (mg/dL)	SD (mg/dL)	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%
Level 2 control solution	200	118.2	3.3	2.8%

Day-to-Day Precision - 10 Meters, 2 lots of test strips, and 3 control solutions (Level 1, 2, and 3) were prepared. Each control was tested twice a day, once in the morning and once in the afternoon consecutively for 10 days.
(N=10 Meter x 2 Lots x 2 tests x10 days =400)

Control solution	N	mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	400	41.8	3.1	7.5%
Level 2	400	120.7	3.1	2.6%
Level 3	400	349.8	7.2	2.1%

b. *Linearity assay reportable range:*
A 25 mL venous whole blood sample was treated with heparin vacuum tube. The blood supplemented with β-D-glucose to prepare seven different blood glucose levels (20-50 mg/dL, 51-80 mg/dL, 81-120 mg/dL, 121-200 mg/dL, 201-300 mg/dL, 301-400 mg/dL, and 400-600 mg/dL). A total of 630 tests were performed to determine the linear regression in three test strip lots.
For each strip lot, N=3 tests/day x 10 days x 7 glucose ranges=210

The linear regression was as follows:

N=	630 (210X3Lot)
Slope	0.9809
Y-intercept	0.8180
R^2	0.9973

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The device was traceable to a laboratory YSI 2300D analyzer. The YSI 2300D analyzer was calibrated before use and the calibrator was manufactured gravimetrically and provided from the instrument supplier.The YSI 2300D analyzer is validated by using the international standard reference material (NIST 965b) every year.
Stability characteristics of the level 2 and level 3 control solutions were determined by performing real-time stability studies and the shelf life could be up to 19 months

at the room temperature.

d. *Detection limit:*
Data was provided to support a reportable range of 20-600 mg/dL.

e. *Analytical specificity:*
Hematocrit interference was evaluated by adjusting the glucose and hematocrit levels of venous blood samples from several donors. The venous blood samples were glucolyzed/spiked to 4 glucose concentrations and the hematocrit levels were adjusted to 20%, 30%, 40%, 50% and 60%. For each hematocrit level, the linear regression was determined by 40 testing results, N=2 times x 5 meters x 4 glucose ranges=40. The maximum percent bias was calculated by comparing to the YSI reading and shown on each linear regression. The acceptance criteria of Hematocrit interference test is: bias $\leqq$15 mg/dL when glucose concentration <75 mg/dL and bias $\leqq$15% when glucose concentration ≥75 mg/dL. Results were summarized in the following table. The device was claimed to use blood samples having hematocrit concentrations ranging from 20% to 60%.

Strip lot #	Hematocrit %	Slope	Y-intercept	R^2	% Bias
012072901	20%	1.1302	-0.1549	0.9994	11.5
	30%	1.1020	-1.2248	0.9992	8.2
	41%	0.9581	6.7717	0.9967	-0.3
	49%	0.8948	-0.6686	0.9984	-9.9
	60%	0.8800	-1.9043	0.9994	-11.7
012072701	20%	1.1257	0.1220	0.9992	11.3
	30%	1.0620	7.2361	0.9994	9.4
	41%	1.0009	1.1845	0.9977	0.7
	49%	0.8875	-0.7334	0.9991	-10.3
	60%	0.8674	-1.9611	0.9991	-13.1

f. *Assay cut-off:*
N/A

2. System Accuracy studies:

a. *Accuracy/Method comparison with predicate device at sites 1, 2, and 3:*

A total 153 diabetes patients were taken capillary blood from a fingertip, palm, and forearm using the EG V1 Pro system at three sites. A healthcare professional performed the tests using the EG V1 Pro meter and the YSI 2300 analyzer. The glucose range of testing values among these samples was 50-517 mg/dL. Meter versus YSI at each site met the ISO 15197 requirement of ninety-five percent (95 %) of the individual glucose results falling within ±15 mg/dL of the laboratory test at glucose concentrations <75 mg/dL and within ± 20 % at glucose concentrations ≥75 mg/dL. These results were summarized in the following tables.

System accuracy professional results for glucose concentrations < 75 mg/dL

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

System accuracy professional results for glucose concentrations ≥ 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%)

Method comparison studies were performed by using alternative site testing (AST) samples compared to YSI. The AST samples from the thenar, hypothenar, and forearm taken by a professional were tested. Each linear regression was calculated and shown in the following table:

Comparison	N	Range(mg/dL)	Slope and Y-intercept	R^2
Finger(professional) vs. YSI	153	58.5 – 433.5	Y=1.0190X-2.9299	0.9823
Thenar(professional) vs. YSI	153	55 - 459	Y=1.0101X-0.6506	0.9719
Hypothenar(professional) vs. YSI	153	53 - 517	Y=1.0537X-7.1471	0.9673
Forearm(professional) vs. YSI	153	50 - 514	Y=1.0282 X-3.9814	0.9650
Venous vs. YSI	153	59 - 432	Y=0.9874 X+1.5835	0.9744

The comparison with the predicate device, the linear regressions was as follows: EG V1 Pro vs. predicate device: Y = 0.9859X +3.5632, R^2= 0.9387

b. *Matrix comparison:*
N/A

3. Clinical studies:
   a. *Clinical Sensitivity:*
   N/A

   b. *Clinical specificity:*
   N/A

   c. Other clinical supportive data (when a. and b. are not applicable):
   see section 2.a.

4. Clinical cut-off:
   N/A

5. Expected values/Reference range:
6. The expected blood glucose levels for an adult (referenced from American Diabetes Association. Standards of medical care in diabetes-Table 8. Diabetes care. 2008; S18.):

Time	Range (mg/dL)
Before meal or fasting	70-130
Post -meal	Less than 180

7. PDI® SUPER SANI-CLOTH® Germicidal disposable wipes with EPA registration# 9480-4 was validated demonstrating complete inactivation of live virus. It demonstrated that there was no change in performance or in the external materials of the meter and lancing device after 11,000 cleaning and disinfection cycles designed to simulated 3 years for professional use.

N. Proposed Labeling:

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

O. Conclusion:

The EG V1 Pro Self Monitoring Blood Glucose System has the same intended use and similar technological characteristics as the Bayer Contour Self Monitoring Blood Glucose System (k062058) marketed by BAYER HEALTHCARE. Moreover, bench testing contained in the submission demonstrated that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the EG V1 Pro Self-Monitoring Blood Glucose System is substantially equivalent to the predicate devise.

510(k) SUMMARY for
EG V1 (BL) Self Monitoring Glucose Test System

A. Submitter's information

Company: EPS Bio Technology Corp.
Address: No. 8, R&D RD. III, Hsinchu Science Park Hsinchu City, Taiwan, R.O.C.
Contact Name: Mr. Y.C. Lei, General Manager
Phone: 886-3-6686868
Fax: 886-3-6686866

B. Measured:

Glucose

C. Type of Test:

Quantitative; electrochemical biosensor

D. Proprietary and Established Names:

EG V1 (BL) Self-Monitoring Blood Glucose Test System

E. Common or Usual Name:

Glucose Test System

F. Regulatory Information:

1. Regulation section:
   21 CFR 862.1345, Glucose Test System
   21 CFR 862.1660, Quality control materials (assayed and unassayed)

2. Classification:
   Class II
   Class I, reserved

3. Product code:
   NBW, System Test, Blood Glucose, Over the Counter
   LFR, Glucose Dehydrogenase, Glucose
   JJX, Single (Specified) Controls (assayed and Unassayed)

4. Panel:
   Chemistry 75

G. Intended Use:

1. Intended use(s):
   See Indications for Use below

2. Indication(s) for use:

The **EG V1 (BL) Self Monitoring Blood Glucose Test System** is intended for the quantitative measurement of glucose in fresh capillary whole blood from 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 be only used during steady-state blood glucose conditions.
The system consists of the **EG V1 (BL) meter** and the **EG test strips**. The EG V1 (BL) meter only is used with the EG V1 test strips to quantitatively measure glucose in fresh capillary whole blood from fingertip, palm, or forearm.
The **EG Glucose Control Solution**
For use with EG V1(BL) Blood Glucose Self Monitoring System as a quality control check to verify the accuracy of blood glucose test results.

3. Special conditions for use statement(s):

EG V1 (BL) Self Monitoring Blood Glucose Test System:
For Over-the-Counter use. Not for use with newborns.

Alternative site testing (AST) can only be used during steady-state blood glucose conditions. AST (forearm) 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.

Measurements from alternative site testing should never be used to calibrate a continuous glucose monitor (CGM) or entered into insulin dose calculators for insulin dosing recommendations.

4. Special instrument requirements:

EG V1(BL) Blood Glucose Meter.

H. Device Description:

The EG V1 (BL) Self-Monitoring Blood Glucose System consists of the EG V1 (BL) Blood Glucose Meter, EG Glucose Test Strips, Auto-Lancet Device and EG Level 2 Control Solution. (Please refer to the IFU for the product picture)

I. Substantial Equivalence Information:

1. Predicate device name(s):
ASCENSIA CONTOUR BLOOD GLUCOSE METER, MODEL 7151; REAGENT STRIP, MODEL 7080

2. Device Company
BAYER HEALTHCARE

3. Predicate 510(k) number(s):
k062058

4. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection method	Amperometry	Amperometry
Enzyme	Glucose Dehydrogenase (FAD)	Glucose Dehydrogenase (FAD)
Sample volume	≥ 0.6 uL	≥ 0.6 uL
Temperature range	10-40^{0}C	10-40^{0}C
Memory capability	480 tests with date and time	480 tests with date and time
Hematocrit range	20-60%	20-60%
Power	3V CR2032 batteries	3V CR2032 batteries

Differences		
Item	Device	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)

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

1. ISO 15197:2003, In Vitro Diagnostic Test Systems – Requirements for Blood Glucose Monitoring Test Systems for Self Managing Diabetes Mellitus.
2. ISO 14971:2007, Medical Devices – Application of Risk Management to Medical Devices.
3. EN 13640:2002, Stability Testing of In Vitro Diagnostic Reagents.
4. IEC 60601-1-2:2004, Medical electrical equipment - Part 1: General requirement for safety; Electromagnetic compatibility -Requirements and tests.
5. IEC 61010-2-101:2002, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment.
6. IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Safety.
7. CLSI EP7-2A:2005, Interference Testing in Clinical Chemistry.

K. Test Principle:

The EG V1 (BL) Self-Monitoring Blood Glucose System employs a disposable dry reagent strip technology, using glucose dehydrogenase method to quantify glucose. 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 glucose to dehydrogenate and 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 calculated in the EG V1 (BL) Glucose Meter and displayed on the screen after 5 seconds.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within-run Precision – The testing was used by venous blood, which was stored in the heparin blood collection tube. Glucose was glucolyzed/spiked to the blood to prepare 6 different levels of glucose concentration: 20-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, 251-400 mg/dL, and 401~600 mg/dL. For each testing range, 10 meters, 10 pcs of test strips for each meter, and 2 lots of test strips were used.
(N=10 Meters x10 tests x 2 lots =200)

Range (mg/dL)	N	EG V1 SMBG system		
		Mean (mg/dL)	SD (mg/dL)	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%
Level 2 control solution	200	118.2	3.3	2.8%

Day-to-Day Precision - 10 Meters, 2 lots of test strips, and 3 control solutions (Level 1, 2, and 3) were prepared. Each control was tested twice a day, once in the morning and once in the afternoon consecutively for 10 days.
(N=10 Meter x 2 Lots x 2 tests x10 days =400)

Control solution	N	mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	400	41.8	3.1	7.5%
Level 2	400	120.7	3.1	2.6%
Level 3	400	349.8	7.2	2.1%

b. Linearity assay reportable range:

A 25 mL venous whole blood sample was treated with heparin vacuum tube. The

blood supplemented with β-D-glucose to prepare seven different blood glucose levels (20-50 mg/dL, 51-80 mg/dL, 81-120 mg/dL, 121-200 mg/dL, 201-300 mg/dL, 301-400 mg/dL, and 400-600 mg/dL). A total of 630 tests were performed to determine the linear regression in three test strip lots.
For each strip lot, N=3 tests/day x 10 days x 7 glucose ranges=210

The linear regression was as follows:

N=	630 (210X3Lot)
Slope	0.9809
Y-intercept	0.8180
R^2	0.9973

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The device was traceable to a laboratory YSI 2300D analyzer. The YSI 2300D analyzer was calibrated before use and the calibrator was manufactured gravimetrically and provided from the instrument supplier.The YSI 2300D analyzer is validated by using the international standard reference material (NIST 965b) every year.
Stability characteristics of the Level 2 and Level 3 control solutions were determined by performing real-time stability studies and the shelf life could be up to 19 months at the room temperature.

d. *Detection limit:*
Data was provided to support a reportable range of 20-600 mg/dL.

e. *Analytical specificity:*
Hematocrit interference was evaluated by adjusting the glucose and hematocrit levels of venous blood samples from several donors. The venous blood samples were glucolyzed/spiked to 4 glucose concentrations and the hematocrit levels were adjusted to 20%, 30%, 40%, 50% and 60%. For each hematocrit level, the linear regression was determined by 40 testing results, N=2 times x 5 meters x 4 glucose ranges=40. The maximum percent bias was calculated by comparing to the YSI reading and shown on each linear regression. The acceptance criteria of Hematocrit interference test is: bias $\leq$15 mg/dL when glucose concentration <75 mg/dL and bias $\leq$15% when glucose concentration ≥75 mg/dL. Results were summarized in the following table. The device was claimed to use blood samples having hematocrit concentrations ranging from 20% to 60%.

Strip lot #	**Hematocrit %**	Slope	Y-intercept	R^2	% Bias
012072901	20%	1.1302	-0.1549	0.9994	11.5
	30%	1.1020	-1.2248	0.9992	8.2
	41%	0.9581	6.7717	0.9967	-0.3
	49%	0.8948	-0.6686	0.9984	-9.9
	60%	0.8800	-1.9043	0.9994	-11.7

012072701	20%	1.1257	0.1220	0.9992	11.3
	30%	1.0620	7.2361	0.9994	9.4
	41%	1.0009	1.1845	0.9977	0.7
	49%	0.8875	-0.7334	0.9991	-10.3
	60%	0.8674	-1.9611	0.9991	-13.1

f. Assay cut-off:
N/A

2. System Accuracy studies:

a. *Accuracy/Method comparison with predicate device at sites 1, 2, and 3:*

A total 153 diabetes patients performed a fingerstick, palm and forearm using the EG V1 (BL) system at three sites. A patient performed the testing using the EG V1 (BL) meter. A healthcare professional performed the test using the YSI 2300 analyzer. The glucose range of testing values among these samples was 50-517 mg/dL.
Meter versus YSI at each site met the ISO 15197 requirement of ninety-five percent (95 %) of the individual glucose results falling within ±15 mg/dL of the laboratory test at glucose concentrations <75 mg/dL and within ± 20 % at glucose concentrations ≥75 mg/dL. These results were summarized in the following tables.

System accuracy patient results for glucose concentrations < 75 mg/dL

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

System accuracy patient results for glucose concentrations ≥ 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%)

Method comparison studies were performed by using alternative site testing (AST) samples compared to YSI. The AST samples from the thenar, hypothenar, and forearm taken by a patient were tested. Each linear regression was calculated and shown in the following table:

Comparison	N	Range(mg/dL)	Slope and Y-intercept	R^2
Finger(a patient) vs. YSI	153	58.5 – 433.5	Y=1.0100X-0.9679	0.9696
Thenar(a patient) vs. YSI	153	55 - 459	Y=0.9688X+4.8241	0.9481
Hypothenar(a patient) vs. YSI	153	53 - 517	Y=1.0896 X-11.7596	0.9584
Forearm(a patient) vs. YSI	153	50 - 514	Y=1.0263X-4.6425	0.9503

The comparison with the predicate device, the linear regressions was as follows:
EG V1 (BL) vs. predicate device: Y = 0.9859X +3.5632, R^2= 0.9387

b. *Matrix comparison:*
N/A

3. Clinical studies:
   a. *Clinical Sensitivity:*
   N/A

   b. *Clinical specificity:*
   N/A

   c. Other clinical supportive data (when a. and b. are not applicable):
   see section 2.a.

4. Clinical cut-off:
   N/A
5. Expected values/Reference range:
   The expected blood glucose levels for an adult (referenced from American Diabetes Association. Standards of medical care in diabetes-Table 8. Diabetes care. 2008; S18.):

Time	Range (mg/dL)
Before meals or fasting	70-130
Post -meals	Less than 180

6. PDI® SUPER SANI-CLOTH® Germicidal disposable wipes with EPA registration# 9480-4 was validated demonstrating complete inactivation of live virus. It demonstrated that there was no change in performance or in the external materials of the meter and lancing device after 11,000 cleaning and disinfection cycles designed to simulated 4 years for home use.

N. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:
The EG V1 (BL) Self Monitoring Blood Glucose System has the same intended use and similar technological characteristics as the Bayer Contour Self Monitoring Blood Glucose System (k062058) marketed by BAYER HEALTHCARE. Moreover, bench testing contained in the submission demonstrated that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the EG V1 (BL) Self-Monitoring Blood Glucose System is substantially equivalent to the predicate devise.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

EPS Bio Technology Corp.
c/o Y.C. Lei
No. 8 R&D. Road III, Hsinchu Science Park
Hsinchu City, ROC 30077
Taiwan

MAY 2 3 2011

Re: k101037
Trade/Device Name: EG V1(BL) Self Monitoring Blood Glucose Test System, EG V1 Pro Self Monitoring Blood Glucose Test System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, LFR, JJX
Dated: 18 May 2011
Received: 20 May 2011

Dear: Mr. Lei,

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): k101037

Device Name: EG V1 Pro Self Monitoring Blood Glucose Test system

Indication 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.

EG Glucose Control Solution
For use with the EG V1 Pro Blood Glucose Self Monitoring System as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use __V__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use __V__ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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

510(k) k101037

Indications for Use

510(k) Number (if known): k101037

Device Name: EG V1(BL) Self Monitoring Blood Glucose Test system

Indication For Use:

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.

EG Glucose Control Solution
For use with the EG V1 Pro Blood Glucose Self Monitoring System as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use ____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use V . (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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

510(k) k101037