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

A. 510(k) Number:
k070053

B. Purpose for Submission:
New device

C. Measurand:
Whole blood glucose

D. Type of Test:
Quantitative, electrochemical biosensor

E. Applicant:
EPS Bio Technology Corp.

F. Proprietary and Established Names:
EasyPlus mini Self-Monitoring Blood Glucose System (Model R2)

G. 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 – glucose assay
   Class I, reserved – control materials
3. Product code:
   NBW - System, Test, Blood Glucose, Over the Counter
   CGA - Glucose Oxidase, Glucose
   JJX - single (specified) analyte controls (assayed and unassayed)
4. Panel:
   75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):
   See indications for use below.

2. Indication(s) for use:
   The EasyPlus mini Self Monitoring Blood Glucose Monitoring System is intended for in vitro diagnostic use (outside of body). It is indicated to be used by professional healthcare personnel or diabetics at home to measure glucose concentration for aiding diabetes management. The glucose concentration is measured with quantitative capillary whole

blood from the fingertip, and forearm by using Easy Plus mini Monitoring Blood Glucose Monitoring System. The device is not intended for testing neonate blood samples.

EasyPlus mini Meter
The EasyPlus mini Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or forearm. EasyPlus mini Blood Glucose Test Strips must be used with the EasyPlus mini Meter. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

The EasyPlus mini Test Strips
The EasyPlus mini Blood Glucose Test Strips, are intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or forearm. EasyPlus mini Blood Glucose Test Strips must be used with the EasyPlus mini Blood Glucose Meter. Testing is done outside the body (In Vitro diagnostic use). They are indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

The EasyPlus Normal/High Control Solution
For use with the EasyPlus mini meter and EasyPlus mini Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

3. Special conditions for use statement(s):
Alternate site testing (AST) (forearm) 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

The device is not intended for testing neonate blood samples nor is the device intended for testing critically ill patients. The labeling includes the following limitations in which the device should not be used for patients: undergoing oxygen therapy, severely dehydrated, severely hypotensive (low blood pressure), in shock and in hypoglycemic-hyperosmolar sate (with and without ketosis).

4. Special instrument requirements:
Easy Plus mini Self Monitoring Blood Glucose Monitoring System (Model R2)

I. Device Description:
The Easy Plus mini Self Monitoring Blood Glucose System consists of the meter, blood glucose test strips, code card, check strip, control solutions (normal and high), lancing device and lancets.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Roche Accu-Chek Advantage System

2. Predicate 510(k) number(s):
   k032552
3. Comparison with predicate:

Similarities and Differences		
Item	Device	Predicate
Detection Method	Amperometry	Same
Temperature Range	10-40˚C	Same
Sample Type	Fresh Capillary Whole Blood	Same
Power	1.5V AAA Batteries	Same
Sample Site	Fingertip and forearm	Fingertip
Memory	480 tests	100 tests
Test Time	5 seconds	40 seconds
Hematocrit Range	30-55%	20-65%
Humidity	≤90%	≤85%
Measuring Range	20-600 mg/dL	10-600 mg/dL

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

1. CLSI EP5-A, Precision Performance of Clinical Chemistry Devices
2. CLSI EP6-P, Evaluation of the Linearity of Quantitative Analytical Methods; Proposed Guideline
3. CLSI EP7-P, Interference Testing in Clinical Chemistry; Proposed Guideline
4. ISO 15197:2003, In Vitro Diagnostic Test Systems – Requirements for Blood Glucose Monitoring Test Systems for Self Managing Diabetes Mellitus
5. IEC 60601-1-2, Medical Electrical Equipment – Part 1: General Requirement for Safety; Electromagnetic Compatibility – requirements and Tests
6. IEC 61010-1, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 1: General Requirements
7. IEC 60601-2-101, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment
8. IEC 60068-2-64, Environmental Testing- Part 2: Test Methods- Test Fh: Vibration, Broad-band Random (Digital Control) and Guidance
9. IEC 61326 (2002-02) – (for reference), Electrical Equipment for Measurement Control, and Laboratory Use – EMC Requirements
10. ISO 14971:2000, Medical Devices – Application of Risk Management to Medical Devices
11. ISO 15223:2000, Medical Devices – Symbols to be used with Medical Device Labels, Labeling, and Information to be Supplied
12. EN 376:2002, Information Supplied by the Manufacturer with In Vitro Diagnostic

Reagents for Self Testing
13. ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing
14. EN 13640:2002 Stability Testing of In Vitro Diagnostic Reagents
15. ISO 15223:2000, Medical Devices – Symbols to be Used with Medical Device Labels

L. Test Principle:

The EasyPlus mini Self Monitoring Blood Glucose System employs a disposable dry reagent strip technology based on the glucose oxidase method for glucose determination. Each test strip features an electrode containing the enzyme glucose oxidase (Aspergillus niger). 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 glucose oxidase catalyzes the oxidation of glucose to produce gluconic acid. 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 displayed on the meter screen after 5 seconds.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The sponsor evaluated within-day precision of the device using whole blood samples spiked with six different glucose concentrations, two test strip lots lots, and 10 different meters. Ten replicate glucose measurements were tested for each concentration in one day. The results are summarized in the table below.

Summary of results for within-day Precision / mg/dL					
Range	YSI 2300 Mean	Number	EasyPlus mini		
			Mean	SD	CV%
20-50	32	200	42	1.9	4.6
51-110	79	200	81	3.6	4.4
111-150	124	200	122	4.3	3.5
151-250	204	200	202	6.2	3.0
251-400	350	200	345	9.1	2.6
401-600	574	200	574	16.2	2.8

Day-to-day precision was evaluated using three glucose controls with low, normal, and high concentration levels over a ten-day period using ten meters and two test strip lots. Each control was tested twice, once in the morning and once in the afternoon. The results are summarized in the table below.

Control	Number	Mean (mg/dL)	SD (mg/dL)	CV%
Low	400	38	3.1	8.3
Normal	400	111	3.8	3.5
High	400	354	13.3	3.8

b. Linearity/assay reportable range:

The measuring range of the device is 20 - 600 mg/dL. Testing was performed using whole blood supplemented with B-D-glucose to provide samples at seven different blood glucose levels ranging from 15 to 628 mg/dL. The linearity study measured spiked whole blood samples with the device using three test strip lots and the YSI 2300 analyzer. A total of 660 tests (220 x 3 lots) were performed on 5 meters. A regression analysis showed linearity of the EasyPlus mini with a correlation coefficient (r^2) of 0.994 and with a regression equation y = 0.9997X -1.554.

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

The control solutions are prepared at two target concentrations by gravimetric addition of glucose to an aqueous matrix. The glucose concentration of the control solutions are verified with the YSI reference method. The glucose concentrations of the control solutions are traceable to NIST SRM 917b8.

Shelf life studies show the unopened test strips have a 19 month life-span and 3 months shelf-life once a vial of strips is opened. Unopened controls have a 19 month shelf life and are stable for 3 months after first use.

d. Detection limit:

The lower end of the measuring range is 20 mg/dL. See the linearity study above.

e. Analytical specificity:

Common interferences were evaluated by spiking venous blood with glucose to three concentrations (approximately 50, 250 and 500 mg/dL). Each of these glucose concentrations was then spiked with the interfering compound at two concentrations to make the interference samples. Control samples were each spiked with the solvents used to make the interfering samples. The substances and concentrations of the interferents are recommended in CLSI EP7. The sponsor's acceptance criterion for the interference test was a bias ≤15 mg/dL when glucose concentration ≤75 mg/dL and bias of ≤15% when glucose concentration >75 mg/dL. Interference from dopamine and L-dopa was observed when the recommended concentration of these drugs was reached in the blood. Interference was also observed in higher than therapeutic dosages of acetaminophen, gentisic acid, and methyldopa.

No interference effects were observed from the common interfering compounds shown below.

Interfering Substance	Test Concentration mg/dL
Acetaminophen	8
Ascorbic Acid	2.5
Dopamine	2
Gentisic Acid	6
Triglycerides	3000
Bilirubin	1.2
Cholesterol	500
L-Dopa	2
Methyldopa	2
Uric Acid	13

The sponsor evaluated the effect of hematocrit levels on whole blood samples spiked with six hematocrit levels (approximately 20%, 30%, 40%, 50%, 55% and 60%) for glucose values (4 levels) distributed within the measuring range (approximately 26 – 510 mg/dL) of the device. Each sample was run n=10 and the percent bias was calculated compared to the 40% hematocrit samples. Results are summarized in the table below. The claim for the device was for use with samples having hematocrit concentrations ranging from 30% to 55%. The results of the hematocrit study are summarized in the table below:

Strip Lot Number	Hematocrit %	YSI level 1 (mg/dL)	YSI Level 2 (mg/dL)	YSI Level 3 (mg/dL)	YSI Level 4 (mg/dL)	Slope	Intercept	r^2	% Bias
012072901	20	28.8	138.5	281	509	1.162	9.6	.998	25.74
012072901	30	28.8	134	281	512	1.21	-2/66	1.000	11.63
012072901	40	27.1	134	286	514	1.000	0.00	1.000	
012072901	50	25.3	136	281	517.5	0.888	0.11	0.999	-12.76
012072901	55	28.0	137	289	512	.0853	7.84	0.998	-13.95
012072901	60	25.2	137.5	290	516	0.792	0.82	0.997	-23.94
012072701	20	28.8	138.5	281	509	1.154	12.04	0.997	30.58
012072701	30	28.8	134	281	512	1.108	0.93	0.999	12.64
012072701	40	27.1	134	286	514	1.000	0.00	1.000	
012072701	50	25.3	136	281	517.5	0.865	3.43	0.999	-12.95
012072701	55	28.0	137	289	512	0.848	7.06	0.998	-14.62
012072701	60	25.2	137.5	290	516	0.779	0.68	0.997	-27.65

An altitude study was performed with venous whole blood adjusted to nine different glucose concentrations ranging from approximately 26 to 568 mg/dL. One aliquot of each sample was tested on the ground at 160 feet above sea level and the other was tested at 10,000 feet. The result of each sample tested at 10,000 feet was within ±15% of the YSI value. This demonstrates that the meter may be used up to an altitude of 10,000 feet above sea level.

Temperature and humidity studies were performed and showed that the meter can be used at temperatures from 50°F to 104°F and at relative humidity ranging from 38% to 93%.

A sample volume study was performed with venous whole blood adjusted to two glucose concentrations (approximately 150 mg/dL and 375 mg/dL) and verified on the YSI analyzer. The tests were performed on five test strip lots. One aliquot of each sample was tested using seven different sample volumes (0.3, 0.4, 0.5, 0.6, 0.8, 1.0 and 1.5 uL.) The sponsor's acceptance criterion was that value of each sample tested on the EasyPlus mini should be within +/- 10% of the YSI value. The studies showed that test can be performed with a sample volume of 0.6 uL.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:
The sponsor demonstrated that the EasyPlus mini Blood Glucose Monitoring System intended for use with fingerstick samples is equivalent to the YSI 2300 Analyzer. 179 diabetics performed the test on the device at three clinics. A healthcare professional then performed the test on the EasyPlus mini and the YSI 2300. The glucose values for these samples ranged from 50.6 - 448 mg/dL. In order to fully cover the measuring range, 20 samples were spiked with glucose or allowed to glycolyze. The approximate percent distribution of 199 samples ranging from 21 to 600 mg/dL were as follows: 20-50 mg/dL – 5%; 51-80 mg/dL – 6%; 81-120 mg/dL – 22%; 121-200 mg/dL – 35%; 201- 300 mg/dL – 21%; 301-400 – 5.5%; and 401-600 mg/dL – 5.5%. Based on data analysis, device met the minimum system accuracy requirement established according to the ISO 15197 guidelines, which is 95% of the individual glucose results falling within ±15 mg/dL of the results of the reference procedure at glucose concentrations <75 mg/dL and within ± 20 % at glucose concentrations ≥75 mg/dL. These results are summarized in the table below.

Accuracy results for glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
3/14 (21%)	11/14 (78%)	14/14 (100%)

Accuracy results for glucose concentration ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20%
69/185 (37%)	127/185 (69%)	166/185 (90%)	183/185 (98%)

Method comparison studies were performed using alternate site testing (AST) samples compared to professional fingerstick samples. The studies were performed

using professional and participant AST samples taken from the forearm. A total of 118 samples were tested at three sites. Regression analysis of the values generated shown below indicated correlation between the finger and the forearm.

Comparison	Number	Range (mg/dL)	Slope and y-intercept	r^2
Forearm vs. finger	118	34 – 600	y=0.986 +5.684	0.991

The sponsor conducted a consumer study at a fourth site with 70 patients to evaluate the accuracy of glucose measurement between the lay-user and the healthcare professionals.
The lay users followed the package insert instructions intended for use in the U.S. They collected blood from the fingertip and forearm and performed the glucose test on the EasyPlus mini. The range of glucose values for these samples was 74 – 247 mg/dL. A healthcare professional then performed the test on the EasyPlus mini and the YSI 2300. Regression analysis of the values generated shown below indicated that lay users could obtain glucose results similar to results obtained by healthcare professionals.

Comparison	Number	Range (mg/dL)	Slope and y-intercept	r^2
Finger (patient vs. YSI)	70	74-247	y=0.979 +1.53	0.922
Finger (professional vs. YSI)	70	74-247	y=1.004 -0.65	0.934
Forearm vs. Finger	70	74-247	y=1.007 +2.86	0.922

b. Matrix comparison:

Not applicable.

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):

See 2a. above.

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:
   The labeling includes a reference for expected values from the literature as follows: Expected blood glucose levels for people without diabetes (American Diabetes Association, Standards of Medical Care for Patients with Diabetes Mellitus, Diabetes Care, 25(2002), p. S37.)

Time Range	**(mg/dL)**
before breakfast	70-105
before lunch or dinner	70-110
one hour after meals	less than 160
two hours after meals	less than 120
between 2 and 4 AM	greater than 70

N. Instrument Name:

EasyPlus mini Self Monitoring Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:
   Each test strip is single use and must be replaced with a new strip for each additional reading.

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:
   This device is intended to be used with capillary whole blood from the fingertip and forearm. Since the whole blood sample is applied directly to the test strip, there are no special handling or storage issues.

5. Calibration:
   The meter automatically detects the code number when a test strip is inserted. The labeling instructs the user to match the code number the meter displays to the code

number on the test vial. If the numbers do not match, or if no number appears, the user is instructed to try another test strip. If this fails the user is instructed to try a new vial of strips and to call customer service if this also fails.

6. Quality Control:
   Glucose control solutions at two different concentrations should be run with this device. They are included in the device. When a test strip is inserted into the meter, the control mode can be activated. This prevents control results from being stored in the internal memory as a patient sample. An acceptable range for each control level is printed on the test strip vial label. The user is referred to the troubleshooting section of the owner's manual if control results fall outside these ranges.

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

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.