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

A. 510(k) Number:
k081796

B. Purpose for Submission:
Clearance of a new device

C. Measurand:
Whole blood glucose

D. Type of Test:
Whole blood glucose concentration through a quantitative amperometric assay (Glucose Oxidase)

E. Applicant:
EPS Bio Technology Corp.

F. Proprietary and Established Names:
EasyPlus mini R2N Self-Monitoring Blood Glucose Test System

G. Regulatory Information:
1. Regulation section:
   21 CFR § 862.1345, Glucose Test System
   21 CFR § 862.1660, Quality control material (assayed and unassayed)

2. Classification:
   Class II
   Class I (reserved)

3. Product code:
   NBW, CGA
   JJX

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 R2N Self Monitoring Blood Glucose Test System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from

the fingertips or forearm. 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 R2N Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips or forearm. EasyPlus mini R2N Blood Glucose Test Strips must be used with the EasyPlus mini R2N 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 R2N 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 R2N Blood Glucose Test Strips must be used with the EasyPlus mini R2N 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 mini R2N Glucose Normal/High Control Solution are for use with the EasyPlus mini R2N meter and EasyPlus mini R2N 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):
   - Not for use on critically ill patients, dehydrated patients or hyperosmolar patients
   - Not for neonatal use
   - Not for screening or diagnosis of diabetes mellitus
   - Alternative site testing is for use at times of steady state only

4. Special instrument requirements:
   EasyPlus mini R2N Self-Monitoring Blood Glucose Test System

I. Device Description:
The EasyPlus mini R2N Self-Monitoring Blood Glucose System consists of the EasyPlus mini R2N Blood Glucose Meter, EasyPlus mini R2N Glucose Test Strips, Auto-Lancet Device, Check Strip and Control Solution. The control solutions available are used to test the performance of the device.

J. Substantial Equivalence Information:
1. Predicate device name(s):
   EPS Bio Technology Corp., EasyPlus Self-Monitoring Blood Glucose System

2. Predicate 510(k) number(s):
   k061992

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection method	Amperometry	Amperometry
Enzyme	Glucose oxidase (Aspergillus niger)	Glucose oxidase (Aspergillus niger)
Mediator	Potassium ferricyanide	Potassium ferricyanide
Electrode	Carbon electrode	Carbon electrode
Test time	5 seconds	5 seconds
Temperature range	10-40^{0}C	10-40^{0}C
Humidity range	R.H. $\leq$ 90%	R.H. $\leq$ 90%

Differences		
Item	Device	Predicate
Sample volume	$\geq$ 0.6 uL	$\geq$ 2.0 uL
Test range	20-600 mg/dL	30-550 mg/dL
Coding	One Code	Code card
Hematocrit range	20-60%	30-55%
Memory capability	480 tests with date and time	100 tests with date and time
Power	3V 2X CR2032 batteries	1.5V (AAA) batteries
Battery life	Approx. 2000 tests	Approx. 1000 tests
Size L x W x H (inch)	3.5"x 2.1"x 0.97"	3.2"x 2"x 0.7"
Weight	2.05 oz (without batteries)	1.6 oz (without batteries)

K. Standard/Guidance Document Referenced (if applicable):
- CLSI EP5-A, Precision Performance of Clinical Chemistry Devices
- CLSI EP6-A, Evaluation of the Linearity of Quantitative Analytical Methods; Proposed Guideline
- CLSI EP7-A, Interference Testing in Clinical Chemistry; Proposed Guideline
- ISO 15197:2003, In Vitro Diagnostic Test Systems – Requirements for Blood Glucose Monitoring Test Systems for Self Managing Diabetes Mellitus
- ISO 14971:2000, Medical Devices – Application of Risk Management to Medical Devices
- EN 13640:2002 Stability Testing of In Vitro Diagnostic Reagents

L. Test Principle:
Glucose measurement is based on electrical potential caused by the reaction of glucose with the reagents contained on the strip's electrodes. The glucose in the sample is oxidized by the enzyme glucose oxidase, and the current resulting from this enzymatic reaction is measured and converted to glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample.

M. Performance Characteristics (if/when applicable):
1. Analytical performance:
   a. *Precision/Reproducibility:*

   Within-Run

   The testing was conducted using venous blood, collected in a heparin blood collection tube. Glucose was added to the blood to prepare 6 different levels of glucose for the testing. The glucose concentration ranges were: 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 test strips for each meter, and 2 lots of test strips were used. (N=10 Meter x10 tests x 2 lots =200)

Range (mg/dL)	N	Lot: 021074801		
		Mean (mg/dL)	SD (mg/dL)	CV (%)
20~50	100	53.8	1.57	2.92%
51~110	100	76.0	1.98	2.61%
111~150	100	126.8	3.28	2.59%
151~250	100	214.6	7.05	3.29%
251~400	100	363.0	8.17	2.25%
401~600	100	561.6	12.39	2.21%
Normal control solution	100	111.6	3.92	3.51%

Range (mg/dL)	N	Lot: 021075201		
		Mean (mg/dL)	SD (mg/dL)	CV (%)
20~50	100	55.9	2.48	4.44%
51~110	100	77.5	2.80	3.62%
111~150	100	132.3	3.27	2.47%
151~250	100	221.2	5.92	2.67%
251~400	100	368.9	7.74	2.10%
401~600	100	563.4	13.96	2.48%
Normal control	100	119.7	4.38	3.66%

solutio n				

Day-to-Day Precision
10 Meters, 2 lots of test strip, and 3 control solutions of Low, Normal and High
were prepared. Each control was tested twice a day, once in the morning and once
in the afternoon 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 (%)
Low	400	47.1	1.67	3.54%
Normal	400	122.2	4.62	3.78%
High	400	398.5	10.57	2.65%

b. *Linearity/assay reportable range:*
Testing was performed using whole blood supplemented with β-D-glucose to provide
630 samples at blood glucose levels between 14 and 613mg/dL. The range of samples
tested on the meter that gave a numeric result was between 22 and 600mg/dL.
The linear regression was as follows:

N=	630
Slope	1.0263
Y-intercept	-1.6952
R^2	0.9949

The sponsor claims 20 mg/dL as the lowest detectable limit.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The sponsor claims that the device is traceable to a laboratory analyzer which is
calibrated to a glucose standard (NIST SRM 965a).

The two control solutions (normal and high levels) consist of buffered aqueous
solutions of β-D-glucose and non-reactive ingredients. Lot-specific ranges are printed
on the test strip bottle label.

Closed Vial Stability of Control Solution: Three lots of each glucose level of control
solution were tested using an accelerated stability study. The results showed that
during the simulated time frame of 19 months at room temperature, the controls were
within the specified ranges (96 mg/dL – 144 mg/dL for normal level and 240 mg/dL –
420 mg/dL for high level).

Opened Vial Stability of Control Solution: The measured glucose levels of 2 lots of each level of control solution were tested during the use lifetime period (90 days) and were found to be within the specified ranges (96 mg/dL – 144 mg/dL for normal level and 240 mg/dL – 420 mg/dL for high level), and the average bias with respect to the mean value throughout the lifetime is less than ≤20% and a CV of 6%.

d. *Detection limit:*
The measuring range of the system is 20 - 600 mg/dL. This range was verified by the linearity study (above section M.1.b.).

e. *Analytical specificity:*
Spiked whole blood samples containing three levels of glucose (50, 250, and 500 mg/dL), with and without interfering substances, were prepared to test common endogenous and exogenous substances for interference. Levels tested for each interferant (in mg/dL) are summarized below:

Interferent (mg/dL)	Level 1	Level 2	Level 3
Acetaminophen	2	8	15
Ascorbic acid	2.5	3.0	
Dopamine	2	13	
Gentisic acid	6	8	
Ibuprofen	4.2	40	
L-Dopa	2	10	
Methyldopa	1	2	2.5
Sodium Salicylate	30	40	50
Tetracycline	0.4		
Tolbutamide	10	64	100
Bilirubin – unconjugated	1.2		
Cholesterol	500		
Creatinine	1.5	30	
Triglycerides	190	3000	
Uric acid	10	13	14
Galactose	10	20	
Maltose	5	10	
Xylose	10	20	

Interference testing showed that the system results in less than ±10% bias in the presence of high concentrations of interferants even beyond clinically significant ranges.

Positive errors greater than 10% were found in the presence of the following and are presented in the labeling under limitations for healthcare professionals:
*   Acetaminophen (15 mg/dL at glucose levels ≤250 mg/dL)
*   Ascorbic acid (3 mg/dL at glucose levels of 50 mg/dL)
*   Dopamine (13 mg/dL at glucose levels ≥50 mg/dL)

- Gentisic acid (8 mg/dL at glucose levels of 50 mg/dL)
- L-Dopa (10 mg/dL at glucose levels ≥50 mg/dL)
- Methlydopa (1 mg/dL at glucose levels of 50 mg/dL and 2.5 mg/dL at glucose levels of 50 mg/dL)
- Triglycerides (3000 mg/dL at glucose levels of 250 mg/dL)
- Uric acid (14 mg/dL at glucose levels of 50 and 500 mg/dL)

An altitude study was performed with 9 blood samples ranging from 29 to 595 mg/dL and spiked whole blood samples of 60 and 310 mg/dL. Testing was performed at altitudes of 160 feet and 10,360 feet. The test data using capillary blood samples showed that the bias versus YSI at 10,360 feet is the same bias versus YSI as that observed at 160 feet. These data indicate no additional effect due to altitude up to the claimed altitude of 10,000 feet.

Hematocrit interference was evaluated by adjusting the glucose concentrations and hematocrit levels of venous blood samples from several donors. The venous blood samples were spiked to 4 glucose concentrations (50, 120, 260, and 500 mg/dL. The hematocrit levels were adjusted to 0%, 20%, 40%, 50%, 60% and 70%. Each sample was assayed n=10 for each of two strip lots and the maximum percent bias was calculated compared to the 40% hematocrit samples. The sponsor demonstrated that the bias did not exceed ±15 mg/dL when glucose concentration is ≤75 mg/dL and bias did not exceed ±15% when glucose concentration is >75 mg/dL for hematocrit concentrations within the claimed range of 20% to 60%.

f. *Assay cut-off*:
   Not Applicable.

2. Comparison studies:
   a. *Method comparison with predicate device*:
      To demonstrate the accuracy performance of the EasyPlus mini R2N Self-Monitoring Blood Glucose Test System a total of 156 diabetes patients performed a finger stick and collected blood from the forearm using the EasyPlus mini R2N system at 3 sites. A healthcare professional then performed the test on the EasyPlus mini R2N and the YSI 2300 analyzer. The range of tested values for these samples was 74.2-486 mg/dL. In order to fully cover the measuring range, 9 of the samples were spiked with glucose or allowed to glycolyze. The total 165 (156+9) samples ranged in concentration from 32 to 591 mg/dL. Each sampling site met the ISO 15197 requirement of ninety-five percent (95 %) of the individual glucose results falling within ±15 mg/dL of the results of the manufacturer's measurement procedure at glucose concentrations for samples <75 mg/dL and within ± 20 % at glucose concentrations ≥75 mg/dL. Results are summarized below:

Linear Regression	Y=1.0263x – 1.6952
R^2	0.9949

Lay User	Fingerstick vs. YSI	Forearm vs. Fingerstick
Total	150/156 (96%)	148/156 (95%)

Professional	Fingerstick vs. YSI	Forearm vs. Fingerstick
Total	160/165 (97%)	150/156 (96%)

    b. Matrix comparison:
Not applicable. Capillary whole blood is the only indicated 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):
The sponsor provided a readability study that indicated that the user manual, test strip labeling, and control solution labeling is at an 8th grade reading level or below.

4. Clinical cut-off:
Not Applicable.

5. Expected values/Reference range:
The sponsor included the following expected values for normal glucose levels in their strip labeling:

70-110 mg/dL
Two-hours after meals: less than 120 mg/dL

American Diabetes Associations: Standards of Medical Care for Patients with Diabetes Mellitus, Diabetes Care, 25(2002), p.S37.

N. Instrument Name:
EasyPlus mini R2N Self-Monitoring Blood Glucose Test System

O. System Descriptions:
1. Modes of Operation:
Each test strip is single use and must be replaced with a new strip for additional readings.

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. <u>Software</u>:
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 finger, palm, and forearm. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:
   This meter is a no code meter. A single calibration code has been selected to be the code for all test strips for the meter which removes the need to manually code the meter.

6. Quality Control:
   The sponsor has two levels of controls available for this meter with both levels coming with the kit and also being available through the distributor. When a test strip is inserted into the meter, a control can be run. An acceptable range for each control level is printed on the test strip vial label. The user is referred to a troubleshooting section at the end of the control test instructions of the owner's manual to identify possible reasons control results fall outside these ranges.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:
   None.

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.