K081796

JAN 23 2009

EasyPlus mini R2N Self Monitoring Glucose Test System
510(k) SUMMARY

A Submitter's information

Company	EPS Bio Technology Corp
Address	2F, No 49-2, Lane 2, Guang Fu Rd , Sec 2 Hsinchu City, Taiwan, R O C
Contact Name	Mr Y C Lei, General Manager
Phone	886-3-5752522
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B Measured

Glucose

C Type of Test

Quantitative, electrochemical biosensor

D Proprietary and Established Names

EasyPlus mini R2N 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
CGA, Glucose Oxidase, 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 **EasyPlus mini R2N Self Monitoring Blood Glucose Test System**
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**
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**
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**
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)

For Over-the-Counter use Not for use with newborns

Alternate 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

4 Special instrument requirements

EasyPlus mini R2N Blood Glucose Meter

H 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 (Please refer to the IFU for the product picture)

I Substantial Equivalence Information

1 Predicate device name(s)
EasyPlus Self-Monitoring Blood Glucose System

2 Device Company
EPS Bio Technology Corporation

3 Predicate 510(k) number(s)
k061992

4 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
Hematocrit range	20-60%	30-55%
Sample volume	≥ 0 6 uL	≥ 2 0 uL
Temperature range	10-40^{0}C	10-40^{0}C
Humidity range	R H ≤ 90%	R H ≤ 90%
Coding	One Code	Code card
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

Differences		
Item	Device	Predicate
Test range	20-600 mg/dL	30-550 mg/dL
Test time	5 seconds	5 seconds
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)

J Standard/Guidance Document Referenced (if applicable)

1 CLSI EP5-A, Precision Performance of Clinical Chemistry Devices
2 CLSI EP6-A, Evaluation of the Linearity of Quantitative Analytical Methods, Proposed Guideline
3 CLSI EP7-A, 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

K Test Principle

The EasyPlus mini R2N 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 measured by the EasyPlus mini R2N Glucose Meter and displayed on the screen after 5 seconds

L Performance Characteristics (if/when applicable)

1 Analytical performance

a Precision/Reproducibility

Within-run – The testing was used by venous blood, which comes with heparin blood collection tube Glucose was added to the blood to prepare 6 different levels of glucose

concentration 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 PCs of 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 mg/dL	100	53 8	1 57	2 92%
51~110 mg/dL	100	76 0	1 98	2 61%
111~150 mg/dL	100	126 8	3 28	2 59%
151~250 mg/dL	100	214 6	7 05	3 29%
251~400 mg/dL	100	363 0	8 17	2 25%
401~600 mg/dL	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 mg/dL	100	55 9	2 48	4 44%
51~110 mg/dL	100	77 5	2 80	3 62%
111~150 mg/dL	100	132 3	3 27	2 47%
151~250 mg/dL	100	221 2	5 92	2 67%
251~400 mg/dL	100	368 9	7 74	2 10%
401~600 mg/dL	100	563 4	13 96	2 48%
Normal control solution	100	119 7	4 38	3 66%

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*
A blood sample of 25 mL was taken, treated with heparin vacuum tube, to be set for a day Testing was performed using whole blood supplemented with β-D-glucose to provide samples at 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 210 tests were performed using 10 meters among the seven glucose ranges per each strip lot

The linear regression was as follows

N=	630 (210X3Lot)
Slope	1 0450
Y-intercept	-1 2505
R^2	0 9950

c *Traceability, Stability, Expected values (controls, calibrators, or methods)*
The device is traceable to a laboratory YSI 2300D analyzer Calibrate YSI 2300D analyzer before its use and the calibrators are manufactured gravimetrically and provided from the instrument supplier
Execute the validation of YSI 2300D analyzer by using this international standard reference material (NIST 965a) every year
Stability characteristics of the Normal and High control solutions were determined by using real-time stability studies to determine the storage stability at room temperature to be 19 months

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 concentrations and hematocrit levels of venous blood samples from several donors The venous blood samples spiked to 4 glucose concentration levels described in the following table The hematocrit levels were adjusted to 0%, 20%, 40%, 50%, 60% and 70% Each sample was run n=10 for each strip lot and the maximum percent bias was calculated compared to the 40% hematocrit samples The acceptance criteria of Hematocrit interference test is bias $\leqq$15 mg/dL when glucose concentration $\leqq$75 mg/dL and bias $\leqq$15% when glucose concentration $>$75 mg/dL Results are summarized in table as below After analysis of this studie, the claim for the device was for use with samples having hematocrit concentrations ranging from 20% to 60%

Strip lot #	Hematocrit %	YSI Labeled Value, mg/dL				Slope	Y-intercept	R^2	% Bias
		Level1	Level2	Level3	Level4				
012072901	0%	54 85	122 5	267 0	494 0	0 9874	51 745	0 9697	29 51
	20%	45 25	119 5	269 0	497 0	0 9461	7 2842	0 9982	-1 18
	40%	47 55	127 5	270 0	505 5	0 9896	-3 4003	0 9982	-2 21
	50%	47 50	125 5	264 0	504 0	0 9529	-4 1426	0 9974	-4 61
	60%	50 05	120 5	264 5	509 5	0 9296	7 5074	0 9992	-0 47
	70%	50 55	118 0	258 5	505 0	0 7149	17 894	0 9944	-13 46
012072701	0%	54 85	122 5	267 0	494 0	1 0812	43 438	0 9811	34 01
	20%	45 25	119 5	269 0	497 0	0 9400	8 8823	0 9968	-0 45
	40%	47 55	127 5	270 0	505 5	1 0130	-7 8632	0 9981	-2 75
	50%	47 50	125 5	264 0	504 0	0 9423	-1 8592	0 9992	-3 97
	60%	50 05	120 5	264 5	509 5	0 9377	4 4687	0 9985	-0 59
	70%	50 55	118 0	258 5	505 0	0 6798	26 641	0 9973	-10 74

f Assay cut-off
N/A

2 Comparison studies

a Method comparison with predicate device
Site 1,2,3.
Accuracy / Method comparison at sites 1,2,3
A total 156 diabetes patients performed a finger stick and 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 on the EasyPlus mini R2N SMBG system The distribution of total 165 samples is described as below:

Glucose concentration	Number of sample	% of sample
<50mg/dL	6	3 6
50-80 mg/dL	8	4 8
81-120 mg/dL	49	29 7
121-200 mg/dL	57	34 5
201-300 mg/dL	33	20 0
301-400 mg/dL	5	3 0
>400 mg/dL	7	4 2

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

results of the manufacturer's measurement procedure at glucose concentrations for samples <75 mg/dL and within ± 20 % at glucose concentrations ≥75 mg/dL These results are summarized in the table below

System accuracy results for glucose concentrations < 75 mg/dL

Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL
7/8(87 5%)	7/8(87 5%)	8/8(100 0%)

System accuracy results for glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
56/157(35 67%)	103/157 (65 61%)	138/157(87 90%)	151/157 (96 18%)

Method comparison studies were performed by using alternate site testing (AST) samples compared to professional finger stick samples The studies were performed by using professional and participant AST samples take from the forearm

The linear regressions were as follows

Comparison	N	Range(mg/dL)	Slope and Y-intercept	R^2
Finger vs YSI (professionals)	156	74 2-486	Y=1 0470X-3 9092	0 9540
Finger vs YSI (lay users)	156	74 2-486	Y=1 0307X-2 8876	0 9471
Thenar vs Finger(professionals)	156	71 0-566	Y=1 0113X+3 2591	0 9610
Thenar vs Finger(lay users)	156	71 0-566	Y=1 0072X+6 7177	0 9539
Hypothenar vs Finger(professionals)	156	71 0-566	Y=1 0642X-2 7188	0 9617
Hypothenar vs Finger(lay users)	156	71 0-566	Y=1 0421X+1 0330	0 9684
Forearm vs Finger(professionals)	156	71 0-566	Y=0 9144X+16 121	0 9448
Forearm vs Finger (lay users)	156	71 0-566	Y=0 9410X+15 266	0 9163

And compare with predicate device, the linear regressions was as follows
EasyPlus mini R2N vs predicate device Y = 1 0431X -1 1192, R^2= 0 9785

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
Expected blood glucose levels for people without diabetes (refereced from American Diabetes Associations Standards of Medical Care for Patients with Diabetes Mellitus, Diabetes Care, 25(2002), p S37)

Time	Range (mg/dL)
Before meals or Fasting	70-110
2 hour after meals	Less than 120

N Proposed Labeling
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809 10

O Conclusion
The EasyPlus mini R2N Self Monitoring Blood Glucose System has the same intended use and similar technological characteristics as the EasyPlus Self Monitoring Blood Glucose System (k061992) marketed by EPS Bio Technology Corp , Moreover, bench testing contained in the submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness Thus, the EasyPlus mini R2N Self-Monitoring Blood Glucose System is substantially equivalent to the predicate devise

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
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Taiwan, R O C

JAN 23 2009

Re k081796
Trade Name EasyPlus mini R2N Self-Monitoring Blood Glucose Test System
Regulation Number 21 CFR 862 1345
Regulation Name Glucose Test System
Regulatory Class Class II
Product Codes NBW, CGA, JJX
Dated January 9, 2009
Received January 12, 2009

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 either class II (Special Controls) or class III (PMA), 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), 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) 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) 443-6597 or at its Internet address
http //www fda gov/cdrh/dsma/dsmamain html

Sincerely yours,

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

Indication for Use

510(k) Number (if known) k081796
Device Name EasyPlus mini R2N
Indication For Use

The **EasyPlus mini R2N Self Monitoring Blood Glucose Test System**
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**
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)
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The **EasyPlus mini R2N Glucose Normal/High Control Solution**
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

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)

Carol C. Benson
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K081796