

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

A. 510(k) Number:

k082328

B. Purpose for Submission:

New device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative, glucose dehydrogenase (FAD-GDH)

E. Applicant:

All Medicus., CO. Ltd.

F. Proprietary and Established Names:

GlucoDR™ Plus System

G. Regulatory Information:

<u>Product Code</u>	<u>Classification</u>	<u>Regulation Section</u>	<u>Panel</u>
NBW – over the counter glucose test system	II	21 CFR 862.1345	75, Chemistry
LFR – glucose test system			
JJX – single (specified) analyte controls (assayed and unassayed)	I (reserved)	21 CFR 862.1660	

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The GlucoDr™ Plus system is intended for in vitro diagnostic use (i.e., for external use only) for quantitative measurement of glucose in venous whole blood and capillary whole blood. Testing sites include traditional fingertip site along with palm, forearm and thigh.

The GlucoDr™ Plus system may be used by healthcare professionals or for self testing by diabetic lay users with diabetes at home as aid in monitoring the effectiveness of diabetes control program.

The GlucoDr™ Plus system is not intended for the diagnosis of or screening for diabetes mellitus nor intended for use on neonates.

The GlucoDr™ Plus control solution is for use with The GlucoDr Plus meters and strips as a quality control check to verify the accuracy of blood glucose test results.

3. Special conditions for use statement(s):

It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

For in vitro diagnostic use only, Over the Counter and prescription use.

The GlucoDr Plus system should not be used for patients who are dehydrated, in shock, critically ill or in a hyperosmolar state.

4. Special instrument requirements:

The GlucoDr Plus meter

I. Device Description:

The GlucoDr Plus system consists of glucose meter, blood glucose test strips and two levels of control solution.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Accu-Chek Aviva System, Roche Diagnostics Corporation

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

k043474

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection Method	Amperometry	Amperometry
Enzyme	Glucose dehydrogenase	Glucose dehydrogenase
Sample type	Capillary or venous blood	Capillary or venous blood
Test time	5 seconds	5 seconds
Control solution	2 range	2 range

Differences		
Item	Device	Predicate
Measurement range	20-600 mg/dL	10-600 mg/dL
Size of Meter	64x87x25 mm(WLH)	53x94x22 mm (WLH)
Sample Volume	1.5 ul	0.6 ul
Coding of Strip	The up/down Button is used to change the code number	Code Chip
Memory Capacity	250 results with date and time	500 results with date and time

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

CLSI EP5-A2: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition (2004)

CLSI EP6-A: Evaluation of Linearity of Quantitative Measurement Procedures, A Statistical Approach: Approved Guideline (2003)

CLSI EP7-A2: Interference Testing in Clinical Chemistry; Approved Guideline (2002)

CLSI EP9-A2: Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (2002)

ISO 15197: 2003, In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

ISO 14971: 2007, Medical devices – Application of risk management to medical devices

EN 13612: 2002, Performance evaluation of in vitro diagnostic medical devices

EN 13640: 2002, Stability testing of in vitro diagnostic medical devices

EN 61010-2-101: 2002, Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipments

FDA Guideline, Review criteria for assessment of portable blood glucose monitoring in vitro diagnostic devices using glucose oxidase, dehydrogenase or hexokinase methodology

L. Test Principle:

The GlucoDr Plus system is based on measurement of electrical currents caused by the reaction of glucose with reagents on the gold electrode strip. Glucose in the blood sample reacts with FAD glucose dehydrogenase and potassium ferricyanide in the test strip, which creates electrical currents. The subsequent electrical currents are proportional to the glucose concentration in the blood and converted to the equivalent glucose concentration by the algorithm programmed in the test meter.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The sponsor performed precision studies using venous whole blood with concentrations between 30 and 400 mg/dL (spiked samples). Testing was performed at 3 sites with 10 meters (3 meters used at site 1 and 2 and 4 meters at site 3) and three lots of test strips were tested with 10 replicates in one day. The results for all three lots are presented in the table below:

Level	Mean of glucose (mg/dL)	Within-run (SD)	%CV
1	41.4	2.52	6.08
2	92.4	2.22	2.40
3	132	3.50	2.65
4	216.6	4.13	1.91
5	329.8	9.03	2.74

In addition, a repeatability of the test strip was tested with control solutions (low, medium and high). Testing was performed at 3 sites with 10 meters (3 meters used at site 1 and 2 and 4 meters at site 3) and three lots of test strips were tested with 10 replicates in one day. The results for all three lots are presented in the table below:

Glucose control solution level	Mean of glucose (mg/dL)	Total imprecision (SD)	Total % CV
Low	46.9	2.99	6.37
Medium	107	3.48	3.24
High	307	7.46	2.43

b. Linearity/assay reportable range:

The linearity of the glucose measurements was demonstrated by comparing prepared blood samples on the GlucoDr test system and a glucose reference method. The seventeen samples ranged in concentration from a low of approximately 20 mg/dL to a high of approximately 600 mg/dL. Three GlucoDr meters and three lots of blood glucose test strips were tested in replicates of three. Linear regression of the comparison data yielded the following relationship:

$$\text{Lot 1 - } y = 0.9961x - 2.0089, R^2 = 0.9987$$

$$\text{Lot 2 - } y = 1.0003x - 1.0572, R^2 = 0.9986$$

$$\text{Lot 3 - } y = 0.9909x - 0.4008, R^2 = 0.9985$$

The reportable range for glucose measurements is 20-600 mg/dL

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

The test strip and control solution stability was assessed by performing real-time and accelerated studies for the shelf life and in use stability. Stability protocols and acceptance criteria were evaluated and found to be acceptable. The claimed shelf life is 18 months and the claimed in-use stability is 90 days for control solution and 4 months for the test strips when stored between 8 – 30 °C.

d. Detection limit:

See linearity/reportable range studies above.

e. Analytical specificity:

Endogenous and exogenous substances were tested for interference on this assay at three glucose concentration (53, 152 and 255 mg/dL). Two test strip lots and 4 meters were used in the study. The sponsor defined interference as a change in glucose measurement from the control greater than 10 mg/dL for glucose concentration <75 mg/dL and greater than 10% for glucose concentration >75 mg/dL. The following substances were tested.

Exogenous Substances	Concentration Showing No Interference (mg/dL)
Acetaminophen	6
Ascorbic Acid	4
Dopamine	13
Ephedrine	30
Ibuprophen	40
L-dopa	13
Methyl dopa	13
Salicylate	50
Tetracycline	4
Tolazamide	100
Tolbutamine	100
Maltose	20

Endogenous Substances	Concentration Showing No Interference (mg/dL)
Bilirubin	4
Creatinine	30
Citric Acid	30
Hemoglobin	500
Oleic Acid	1.4
Palmitic Acid	1.0
Protein –Albumin	6.0
Triglycerides	300
Uric Acid	10

All substances tested except for the ones listed below show no interference at the concentrations tested. The sponsor notes in the labeling that the following substances may affect the test results above concentrations tested; Acetaminophen >6 mg/dL, Ascorbic Acid >4 mg/dL, Total bilirubin >4 mg/dL, Triglycerides >300 mg/dL and Uric acid >10 mg/dL.

Hematocrit study:

The effect of hematocrit was evaluated in a study using samples with 5 glucose concentrations (40-60, 80-120, 150-200, 250-300, and 350-450 mg/dL) and varying hematocrit levels from 20 - 60%. Each glucose level/hematocrit combination was tested on 5 meters using 3 lots of test strips, by comparing the results of samples at each of the varying hematocrit levels to the sample of the same glucose concentration at a normal (40%) hematocrit level. Each glucose level/hematocrit combination was also compared to the corresponding YSI value. The data supports the sponsor's claimed hematocrit range of 20-60%

Altitude study:

An altitude study was performed with four whole blood samples spiked to the following concentration 80-120, 180-200, 280-320 and 380-420 mg/dL. The samples were tested at ground level up to 8,200 feet. All samples met the sponsor's acceptability criterion of the difference between the minimum and maximum result at each concentration range is < 10%. The data submitted supports use of the device up to 8,200 feet.

Temperature and humidity studies were performed and showed that the meter can be used at temperatures from 2-40° C and at a relative humidity from 36 to 85%

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

The consumer study was performed at three POC sites with a total of 130 lay-users. The lay-users ranged in age, education and were about equally divided between males and females. Each participant performed their own fingerstick and tested their blood using the instructions in the User's manual and package insert. A trained professional then performed another fingerstick and tested the blood on the same meter. Blood was collected and measured on an YSI analyzer.

	Number of samples	Linear Regression	r value	Sample Range (mg/dL)	% Clarke Error Grid	
					A	B
Lay-User vs. YSI	130	$y = 0.962x + 7.898$	0.998	34 - 543	96%	4%
Professional vs. YSI	130	$y = 0.9697x + 5.85$	0.998	34 - 543	99%	1%
Lay-user vs. Professional finger stick	130	$y = 0.990 + 2.5622$	0.997	34-543		

System accuracy results for glucose are present in the tables below:

For glucose concentrations ≤ 75 mg/dL

	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Professional	15/17 (88%)	17/17 (100%)	17/17 (100%)
Lay-user	11/17 (65%)	17/17 (100%)	17/17 (100%)

For glucose concentrations > 75 mg/dL

	within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
Professional	91/113 (81%)	108/113 (96%)	113/113 (100%)	113/113 (100%)
Lay-user	91/113 (81%)	108/113 (96%)	112/113 (99%)	113/113 (100%)

Alternate site testing:

The consumer study was performed at one POC site with a total of 51 lay-users. The lay-users ranged in age, education and were equally divided between males and females. Each participant performed a self-test on their finger, palm, arm and thigh testing their blood using the instructions in the User's guide. A trained professional then performed testing on the finger, palm, arm and thigh, testing the blood on the same meter.

	Number of samples	Linear Regression	r value	Sample Range (mg/dL)
Lay-user palm vs Professional finger stick	51	$y = 0.9958x - 2.9256$	0.994	65-320
Lay-user arm vs Professional finger stick	51	$y = 0.9931x - 4.5291$	0.993	65-320
Lay-user thigh vs Professional finger stick	51	$y = 0.9957x - 4.93$	0.993	65-320

System accuracy alternative site Professional and Lay-user results for glucose are present in the tables below:

For glucose concentrations ≤ 75 mg/dL Professional

	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Finger	1/5 (20%)	4/5 (80%)	5/5 (100%)
Palm	0/5 (0%)	1/5 (20%)	3/5 (60%)
Arm	1/5 (20%)	3/5 (60%)	5/5 (100%)
Thigh	0/5 (0%)	3/5 (60%)	4/5 (80%)

For glucose concentrations >75 mg/dL Professional

	within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
Finger	25/46 (54%)	38/46 (83%)	45/46 (98%)	46/46 (100%)
Palm	28/46 (61%)	41/46 (89%)	46/46 (100%)	46/46 (100%)
Arm	29/46 (63%)	44/46 (96%)	46/46 (100%)	46/46 (100%)
Thigh	30/46(65%)	42/46 (91%)	46/46 (100%)	46/46 (100%)

For glucose concentrations ≤ 75 mg/dL Lay-User

	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Finger	1/5 (20%)	4/5 (80%)	5/5 (100%)
Palm	1/5 (20%)	4/5 (80%)	5/5 (100%)
Arm	1/5 (20%)	4/5 (80%)	4/5 (80%)
Thigh	2/5 (40%)	3/5 (60%)	5/5 (100%)

For glucose concentrations > 75 mg/dL Lay-User

	within ± 5%	within ± 10%	within ± 15%	within ± 20%
Finger	32/46(69.6%)	43/46 (94%)	45/46 (98%)	46/46 (100%)
Palm	35/46 (76%)	46/46 (100%)	46/46 (100%)	46/46 (100%)
Arm	39/46 (85%)	46/46 (100%)	46/46 (100%)	46/46 (100%)
Thigh	38/46 (83%)	44/46 (96%)	46/46 (100%)	46/46 (100%)

b. Matrix comparison:

EDTA venous blood samples from 70 patients were assayed on the GlucoDr Plus meter and the YSI using two strip lots. Sample ranged from 65-444 mg/dL. The linear regression for each lot is:

Lot 1 - $y = 0.9851x + 1.389$, $r^2 = 0.9989$

Lot 2 - $y = 0.9888x + 0.7925$, $r^2 = 0.9992$

System accuracy results for glucose are present in the tables below:

For glucose concentrations ≤ 75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
6/8 (75%)	8/8 (100%)	8/8 (100%)

For glucose concentrations > 75 mg/dL

within ± 5 %	Within ± 10 %	within ± 15 %	within ± 20 %
124/132(94%)	130/132(98%)	132/132(100%)	132/132(100%)

23 Lithium Heparin venous blood samples were assayed in triplicate on the GlucoDR Plus meter and the YSI using two strip lots. Samples ranged from 40-400 mg/dL. The resulting linear regressions obtained when using the first sample on each lot are as follows: Lot 1 – $Y = 1.011X + 0.4002$, $r^2 = 0.9987$ and Lot 2 – $Y = 0.9861X + 3.13$, $r^2 = 0.9973$. System accuracy results for the first glucose sample met the ISO criteria of ≤ 75 mg/dL with ± 10 mg/dL and > 75 mg/dL within 20%. All subsequent replicates met the ISO criteria also.

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:

The sponsor included the following Expected Values for people without diabetes in their strip labeling:

Status	Range
Fasting and Before meals	70-100 (mg/dL) (3.9-6.1 mmol/L)
2 hours after meals	Less than 140 mg/dl (7.8 mmol/L)

Source: ADA Clinical Practice Recommendations 2003

N. Instrument Name:

GlucoDr Plus 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.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes X or No

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

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, palm, forearm or thigh and venous whole blood. For capillary whole blood, since the sample is applied directly to the test strip there are no special handling or storage issues. For EDTA and lithium heparin venous whole blood samples must be tested within 15 minutes of draw and the sample should not be stored.

5. Calibration:

Each bottle of test strips has a code number which is used to calibrate the meter. The code number must be verified by turning on the meter using the power button. The code number can not be changed with a test strip inserted into the port. The user confirms that the code number on the test strip bottle matches the code number in the instrument. If they are different then the user changes the number by depressing the power button. The user looks for the code number to begin flashing than releases the power button, this should take approximately one second. Next, the user uses the up/down buttons to adjust the code to the correct number. To save the correct code number the user presses the power button. No further calibrations are required of the user.

6. Quality Control:

The sponsor is providing two levels of control solution with this device. To mark the test result as a control, after the test result is displayed the user is instructed to press the up/down buttons to select the attention event icon. After the attention event icon appears

on the display press the power button to save. This distinguishes control results from actual blood glucose tests in the memory. An acceptable range for each control level is printed on the test strip vial label. If control results fall outside these ranges, the user is referred to a list of troubleshooting steps and the customer care line.

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

Not applicable

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.