

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

**A. 510(k) Number:**

k103329

**B. Purpose for Submission:**

Clearance of new device

**C. Measurand:**

Capillary whole blood glucose

**D. Type of Test:**

Quantitative amperometric whole blood, glucose oxidase

**E. Applicant:**

DELBio Incorporation

**F. Proprietary and Established Names:**

DiaTrue Plus Blood Glucose Monitoring System

DiaTrue Glucose Control Solution

**G. Regulatory Information:**

1. Regulation section:

21 CFR: 862.1345, Glucose Test System

21 CFR 862.1660, Quality control material

2. Classification:

Class II

Class I, reserved

3. Product code:

NBW – System, Test, Blood Glucose, Over the Counter

CGA - Glucose Oxidase, Glucose test system

JJX - Quality Control Material

4. Panel:

75 (clinical chemistry)

**H. Intended Use:**

1. Intended use(s):

Same as indications for use

2. Indication(s) for use:

**DiaTrue Plus Blood Glucose Monitoring System:**

The DiaTrue Plus Blood Glucose Monitoring System is an in vitro diagnostic medical device intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. Testing is done outside the body (in vitro diagnostic use). It is indicated for use at home and should only be used by a single person with diabetes as an aid to monitor the effectiveness of diabetes control and should not be shared. The device should not be used for screening or diagnosis of diabetes or for testing neonates.

**DiaTrue Plus Blood Glucose Meter:**

The DiaTrue Plus Blood Glucose Meter is intended to use for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. Testing is done outside the body. It is indicated for use at home and should only be used by a single person with diabetes as an aid to monitor the effectiveness of diabetes control.

**DiaTrue Plus Blood Glucose Test Strips:**

The DiaTrue Plus Blood Glucose Test Strips are intended to use for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The Blood Glucose Test Strips must be used with the DiaTrue Plus Blood Glucose Meter. Testing is done outside the body. They are indicated for use at home and should only be used by a single person with diabetes as an aid to monitor the effectiveness of diabetes control.

**DiaTrue Glucose Control solution:**

For use with DiaTrue Blood Glucose Meter and DiaTrue Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results. Three levels of control solution are provided: Level I, Level II and Level III.

3. Special conditions for use statement(s):

- For single person, over the counter use
- Not for use in the screening or diagnosis of diabetes
- Not for use in testing neonates
- Not for use on critically ill patients, dehydrated patients, patients in shock, or hyperosmolar patients
- Not for alternative site testing

4. Special instrument requirements:

DiaTrue Plus Blood Glucose Meter

**I. Device Description:**

The DiaTrue Plus Blood Glucose Monitoring System is for single-patient use for the measurement of glucose in whole blood. The system consists of the DiaTrue Plus Blood Glucose Meter, DiaTrue Plus Blood Glucose Test Strips, and three levels of control solution Level I, Level II and Level III. The system does not include a lancing device or lancets.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

ARKRAY GLUCOCARD™ 01 Blood Monitoring System

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

k073416

3. Comparison with predicate:

Similarities		
Item	Proposed Device (DiaTrue Plus Blood Glucose Monitoring System)	Predicate Device (ARKRAY GLUCOCARD™ 01 Blood Monitoring System, K073416)
Intended use	Intended for use in the quantitative measurement of glucose with fresh capillary whole blood as an aid in monitoring the effectiveness of diabetes control program.	Same
Detection Method	Amperometry	Same
Enzyme	Glucose Oxidase	Same
Sample type	Capillary blood	Same
Sample application	Apply blood to end, capillary	Same

	fill	
Measurement unit	mg/dL	Same
Measurement range	20-600 mg/dL	Same
Maximum Altitude	10000 ft	Same
Control solution(s)	Three levels available	Same
Display	Liquid crystal display	Same

Differences		
Item	Proposed Device (DiaTrue Plus Blood Glucose Monitoring System)	Predicate Device (ARKRAY GLUCOCARD™ 01 Blood Monitoring System, K073416)
Hematocrit range	30-55%	30-54%
Minimum Sample Volume	1uL	0.3uL
Test time (sec.)	5	7
Code setting	No-automatic coding. User has to select the matching test strip vial.	Automatic with strip insertion
Memory Capabilities	512 results	360 results
Power Source	2 AAA batteries	One 3V Lithium CR2032
Blood Source	Fingertip	Fingertip and Palm
Weight	90g with battery	45g with battery
Dimension	9.0×6.0×3.5cm	5.0×10.0×1.2 cm

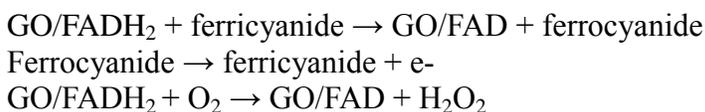
**K. Standard/Guidance Document Referenced (if applicable):**

- ISO 14971:2007. Medical devices-Application of risk management to medical devices.
- ISO 15197. *In vitro* diagnostic test systems. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
- EN 60601-1-1. Medical electrical equipment, Part 1-1. General requirements for safety. Safety requirements for medical electrical systems.
- EN 60601-1-2:2001 (A1:2006). Medical electrical equipment, Part 1-2. General requirements for basic safety and essential performance. Electromagnetic Compatibility.
- EN 61326-1:2006. Electrical equipment for measurement, control, and laboratory use. EMC Requirements. General requirements.
- IEC/EN 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.

**L. Test Principle:**

The test strip chemistry uses Glucose Oxidase (GO), the chemical reaction on strip is as follows:





The test is based on electrochemical biosensor technology and the principle of capillary action. The electrical current generated by the reaction of glucose in the sample with the glucose oxidase enzyme in the strip is measured by the meter and is displayed as the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

The sponsor performed precision studies in accordance with the ISO 15197 and CLSI EP-5A. Venous whole blood adjusted to 5 glucose levels (30-50mg/dL, 51-110mg/dL, 111-150mg/dL, 151-250mg/dL, 251-400mg/dL) were used for within-day precision studies. Each concentration (42% hematocrit level) was tested 10 times each on 10 meters, using 3 test strip lots, (100 total tests divided between 3 strip lots per blood glucose level). Results are summarized below:

Within-Run Precision summary.

	Interval 1 (30-50 mg/dL)			Interval 2 (51-110 mg/dL)			Interval 3 (111-150 mg/dL)		
Test Strip Lot	Lot A	Lot B	Lot C	Lot A	Lot B	Lot C	Lot A	Lot B	Lot C
Grand Mean (mg/dL)	40.4	38.7	36.9	93.9	90.2	88.5	132.3	122.2	120.5
Pool SD (mg/dL)	1.48	1.04	0.92	1.97	2.44	2.34	2.79	2.66	3.09
Pool CV (%)	3.66	2.69	2.50	2.10	2.71	2.64	2.11	2.17	2.56
Overall mean (mg/dL)	38.7			90.9			125		
Over all SD (mg/dL) (95%CI)	1.87 (1.73~2.04)			3.19			5.94		
Overall CV (%)	4.84			3.51			4.75		

	Interval 4 (151-250 mg/dL)			Interval 5 (251-400 mg/dL)		
Test Strip Lot	Lot A	Lot B	Lot C	Lot A	Lot B	Lot C
Grand Mean (mg/dL)	229.8	227.1	214.5	364.7	403.6	371.2
Pool SD(mg/dL)	5.16	4.19	4.77	7.82	8.19	7.54
Pool CV (%)	2.25	1.85	2.23	2.14	2.03	2.03
Overall mean (mg/dL)	223.8			379.8		
Over all SD (mg/dL)	8.18			18.73		
Overall CV (%)	3.66			4.93		

In addition to the study above, the sponsor also evaluated day-to-day precision using control samples with three levels of glucose concentrations (30-50mg/dL, 96-144mg/dL, 280-420mg/dL). Three lots of test strips and 10 meters were used in the study, with 1 test performed on each meter per day for 10 days, for a total of 100 tests per control level (100 total tests divided between 3 strip lots per blood glucose level). Results for each test strip lot are summarized in the tables below:

Table.2 Between-Day Precision summary.

	Low (30-50 mg/dL)			Normal (96-144 mg/dL)			High (280-420 mg/dL)		
Test Strip Lot	Lot A	Lot B	Lot C	Lot A	Lot B	Lot C	Lot A	Lot B	Lot C
Grand Mean (mg/dL)	39.2	42.9	39.1	120.4	119.1	117.3	324.4	299.7	301.2
Pool SD (mg/dL)	2.41	1.75	1.89	4.16	3.43	3.08	7.59	5.69	7.38
Pool CV (%)	6.16	4.07	4.83	3.45	2.88	2.63	2.34	1.90	2.45
Overall mean (mg/dL)	40.4			118.9			308.4		
Over all SD (mg/dL) (95%CI)	2.69 (2.49~2.92)			3.8			13.29		
Overall CV (%)	6.65			3.19			4.31		

*b. Linearity/assay reportable range:*

The sponsor performed linearity studies using adjusted venous blood samples with eight glucose concentrations (15-30mg/d, 31-60mg/dL, 61-100mg/dL, 101-200mg/dL, 201-300mg/dL, 301-400, 401-550, 551-700mg/dL) tested. For each concentration, 10 meters of the candidate device and YSI-2300 were tested in duplicate. The resulting data was compared and the linear regression analyses were as follows:

Linear relationship between DiaTrue Plus and YSI 2300 in three lots of strips ranged between

$$Y = 1.006X - 3.731 \text{ and } Y = 0.998X - 1.428 \text{ where ranges for } R^2 = 0.998 \text{ to } 0.999$$

The study results support the claimed measuring range of these systems as 20-600 mg/dL.

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

Stability characteristics of the test strips were determined using real-time and accelerated studies, using unopened and opened vials. The testing protocol and acceptance criteria were reviewed and found to be adequate. When stored unopened at the recommended storage temperature of 50° F to 77° F (10-25°C) the sponsor claims the test strips are stable for 18 months. Once opened, the test strips are stable for up to 3 months when stored at 50° F to 77° F.

Stability characteristics of the control solutions were determined using real-time and accelerated studies, using unopened and opened vials. The testing protocol and acceptance criteria were reviewed and found to be adequate. The sponsor claims the unopened shelf-life is 18 months at the recommended storage of 50° F to 77°F (10-25°C). Once opened, the control solutions are stable for 3 months when stored at 50° F to 77°F.

*d. Detection limit:*

The measuring range of the system is 20-600 mg/dL. This range was verified by the linearity study.

*e. Analytical specificity:*

**Interference Study:**

Endogenous compounds and drugs:

Interference testing was conducted to determine the effect of selected endogenous and exogenous substances on the test system. The potential interferants were tested at therapeutic or normal ranges and also at above therapeutic or toxic ranges. Venous blood samples at three glucose concentrations (70 mg/dL, 120 mg/dL, and 360 mg/dL) were prepared and divided into a test (dosed) pool and a control pool. Paired differences of glucose measurements between test samples and control samples were calculated to determine the bias. There was less than +/-10% bias for the substances listed below at the listed concentrations.

<b>Interferent</b>	<b>highest test level</b>	<b>Interferent</b>	<b>highest test level</b>
Acetaminophen	20 mg/dL	Bilirubin	20 mg/dL
Ascorbic acid	3 mg/dL	Cholesterol	500 mg/dL
Dopamine	0.1 mg/dL	Creatinine	5 mg/dL
Gentisic acid	2 mg/dL	Glutathione	3 mmol/L
Ibuprofen	50 mg/dL	Triglyceride	3000 mg/dL
Levo-Dopa	13 mg/dL	Urea	260 mg/dL
Maltose	450 mg/dL	Uric acid	20 mg/dL
Methyl dopa	1.5 mg/dL	Tolazamide	8.4 mg/dL
Salicylic acid	60 mg/dL	Tolbutamide	64 mg/dL
Tetracycline	1.5 mg/dL	Lactose	1000 mg/dL
Mannose	1000 mg/dL		

The sponsor states in their labeling that each of the above listed substances do not significantly affect results when at normal or therapeutic concentrations and below in the human body.

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

This study was performed in accordance with ISO 15197.

Testing was completed by comparing the Dia True Plus blood glucose monitoring systems against YSI-2300 glucose analyzer (reference method) .The study was conducted at 3 different clinical sites, with a total of 260 subjects. Three lots of test strip were used in the study.

The fresh capillary whole blood samples from different individuals were used except for blood glucose concentrations < 50mg/dL, where capillary blood samples were allowed to glycolyze. An additional ten spiked venous specimens (specimens are taken from POC sites to represent > 400 mg/dL) were used. All samples were tested twice by health care professionals using the DiaTrue Plus system. However, only one set of these measurements were used for statistical analysis. A venous blood sample was also collected within 5 minutes for testing with the YSI analyzer.

Distribution of sample test results:

Glucose concentration (mg/dL)	Samples(n)	%samples
< 50	23	8.8
50 - 80	35	13.5
80 - 120	41	15.8
120 - 200	79	30.4
201 - 300	34	13.1
301 - 400	24	9.2
> 400	24	9.2

Number and % of results within reference (for concentrations  $\geq 75$  mg/dL)

within $\pm 5$ mg/dL	within $\pm 10$ mg/dL	within $\pm 15$ mg/dL
34/50 (66%)	44/50 (88%)	49/50 (98%)

Assessment: 98% of the individual results are within  $\pm 15$ mg/dL when glucose

concentration is less than 75mg/dL.

Number and % of results within reference (for concentrations  $\geq 75$  mg/dL)

within $\pm 5\%$	within $\pm 10\%$	within $\pm 15\%$	within $\pm 20\%$
77/210 (36.7%)	145/210 (69.0%)	188/210 (89.5%)	207/210 (98.6%)

Assessment: 98.6% of the individual results are within  $\pm 20\%$  when glucose concentration  $\geq 75$ mg/dL.

Criteria from ISO 15197: 95% of the individual glucose results shall fall within  $\pm 15$ mg/dL when glucose concentration less than 75mg/dL and within  $\pm 20\%$  when glucose concentration  $\geq 75$ mg/dL.

Linear regression between test results of YSI and DiaTrue Plus system  
 $Y=1.0251X + 3.3757$ ,  $R=0.9937$

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):*

User study:

Lay users (150 subjects) were given the user manual in English for the DiaTrue Plus blood glucose monitoring system and were given no additional instructions. They were requested to perform the test by themselves and answer the questionnaire. Healthcare professionals took one further measurement (immediately after) with the DiaTrue Plus, and the results between the lay users and health care professionals were compared. An additional blood sample was taken within 5 minutes and was tested by

professionals with the YSI 2300 analyzer for comparison.

Comparison results of 150 American lay user individual values and YSI value.

Glucose concentration < 75 mg/dL:

within ±5mg/dL	within ±10mg/dL	within ±15mg/dL
3/3 (100%)	3/3 (100%)	3/3 (100%)

Glucose concentration ≥ 75 mg/dL:

within ±5%	within ±10%	within ±15%	within ±20%
60/147(40.8%)	101/147(68.7%)	130/147(88.4%)	143/147(97.3%)

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:

Time	Range, mg/dL
Fasting and Before Meals	<100 mg/dL
2 hours after Meals	<140 mg/dL

“Standards of Medical Care in Diabetes 2010”, Diabetes Care, January 2010, vol.33, no Supplement 1, S11-S61.

**N. Instrument Name:**

DiaTrue Plus Blood Glucose Meter

**O. System Descriptions:**

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. Software:

FDA 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:

Single home-use for capillary whole blood testing only. This device is intended to be used with capillary whole blood from the finger only. The whole blood sample is applied directly to the test strip.

5. Calibration:

No automatic coding; the calibration code for the vial of test strips should be selected or verified by the user from the available choices of code numbers programmed in the meter. Users are instructed where to find the calibration code information on the test strip vial label.

6. Quality Control:

The sponsor has three levels of controls that are provided with the meters, When a test strip is inserted into the meter, each control can be measured by following the instructions for "Performing a Control Solution Test" provided in the User's Manuals for the meters. An acceptable range for each control level is printed on the test strip vial label. If the test results fall outside the range printed on the test strip vial, the user is instructed to contact the Customer Care Line at (800) 762-5371 for customer support. The Customer Care service is available 9am-5pm M-F EST

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

**1. Hematocrit Study:**

A study to evaluate the effect from hematocrit was conducted on samples with 6 glucose concentrations (20-50, 50-70, 110-130, 200-250, 350-380 and 520-550

mg/dL) at 5 hematocrit levels (25, 30, 45, 55, and 65%). Each glucose level/hematocrit combination was tested in duplicate on 10 meters using one lot of test strips. Results of samples at each hematocrit level were compared to samples with the same glucose concentration at normal (45%) hematocrit as well as to the corresponding YSI value. All results met the sponsor's acceptance criteria of  $\pm 15\%$  which supports the claimed hematocrit range of 30-55%.

**2. Altitude study:**

An altitude study was performed at elevations up to 10,072 feet with 60 tests each (using 8 meters and one test strip lot) with 6 concentrations of spiked venous whole blood spanning 30 to 600 mg/dL. Sea level results were compared to results at higher elevations and to YSI values, with all results meeting the sponsor's acceptance criteria of  $\pm 10\%$ .

**3. Specimen volume study:**

A sample volume study was performed to verify the test strip sample volume requirement and the test strip fill error requirement established for the BGMS. Three lots of test strips were tested on Spiked or glycolyzed venous whole blood (Hct: 42%) at one glucose concentration of 110-120 mg/dL. Blood at this concentration was applied to strips at 9 target sample volumes of 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, 1.2, 1.5  $\mu\text{L}$ . The sponsor concluded that sample volume of  $\geq 0.9 \mu\text{L}$  produced accurate results (within 5%), samples  $< 0.6 \mu\text{L}$  gave no measurement and samples between 0.6-0.9  $\mu\text{L}$  gave inaccurate results due to insufficient volume of blood. The labeling provides instructions and graphics to assist the user in obtaining and applying an adequate sample volume.

**4. Drop tests and vibration tests;**

These tests were conducted and results analyzed to give the mean, SD and CV before and after the challenge. The sponsor provided the test report to confirm that vibration tests were conducted on 3 meters at random wave form between frequencies of 10-500 Hz on X Y Z axes, 30 minutes per axis.

Results of DiaTrue Plus Blood Glucose Meter showed CVs less than 5% at three glucose levels, and the mean difference % before and after challenge were reviewed and deemed acceptable.

**5. User performance study:**

For the user performance study summarized in section M.2.a above, the participants were asked to complete a questionnaire to evaluate the ease of use of the device and the clarity of the English language labeling. Overall the users indicated that they could successfully perform the test and that the user manual was written clearly.

**6. Readability assessment:**

The sponsor performed a readability assessment of the labeling and states that the user manual, strip insert, and control insert are written at 8th grade level or below based on SMOG analysis.

**7. Temperature and humidity studies**

Temperature and humidity studies were conducted that demonstrated that the devices can be used at temperatures of 10 to 40°C and at a relative humidity of 20 to 90%, and stored at temperatures of 10 to 25°C with a relative humidity of 20 to 75%. The sponsor tested the extreme combinations of temperature and humidity and the results were within the sponsor's acceptance criteria for SD and CV( before and after conducting the humidity exposure test as the SD is < 5 for glucose concentration < 75 mg/dL and CV is < 5% for glucose concentration  $\geq$  75 mg/dL ).

**8. Electromagnetic Compatibility:**

(EMC) testing was performed/passed and a certificate granted to DelBio Incorporation was provided.

**9. Disinfection and Robustness studies**

The device is intended for single-patient use only. Super Sani-Cloth Germicidal Wipes with EPA registration # 9480-4 were validated demonstrating complete inactivation of live virus for use with the meter. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter after 260 cleaning and disinfection cycles designed to simulate 5 years of device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

**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.