

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

A. 510(k) Number:

k130244

B. Purpose for Submission:

Device modifications to add alternative site sampling from the palm, to extend the storage conditions for the test strip and controls, and to add the DiaLife Mini Blood Glucose Management Software, and a USB cable data transmission feature.

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

21 CFR 862.2100, Calculator/data processing module for clinical use

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

JQP - Calculator/data processing module for clinical use

4. Panel:

75 (clinical chemistry)

H. Intended Use:

1. Intended use(s):

See indication(s) for use below.

2. Indication(s) for use:

DiaTrue Plus Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use) at home. It is used for quantitative measurement of glucose level in fresh capillary whole blood sample from the finger and the palm. The alternate site testing can be only used during steady-state blood glucose monitoring. The DiaTrue Plus Blood Glucose Monitoring System is intended for use by a single person and should not be shared. In addition, it is intended for use at home as an aid in monitoring the effectiveness of diabetes control program. It should not be used for the diagnosis or screening of diabetes, nor for the testing of neonates.

The DiaTrue Plus Blood Glucose Test Strips are used with the DiaTrue Plus Glucose meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the finger and the palm.

The DiaTrue Glucose Control Solutions are for use with the DiaTrue Plus Blood Glucose Test Strips and the DiaTrue Plus Glucose meter as a quality control check that the meter and test strip are working together properly, and that the test is performing correctly.

The DiaLife Mini Blood Glucose Management Software is designed for use in the home

with the DiaTrue Plus Blood Glucose Monitoring System to allow users to transmit data from meter to their computer. It is an optional data management software accessory for use with the DiaTrue Plus Blood Glucose Monitoring System.

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
- Alternative site testing (AST) testing should only be done during steady-state times (when glucose is not changing rapidly).
- AST should not be used to calibrate continuous glucose monitors (CGMs).
- AST should not be used for insulin dose calculations.

4. Special instrument requirements:

DiaTrue Plus Blood Glucose Meter

I. Device Description:

The systems consist of three main components: the meter (modified from k103329), test strips (modified from k103329), and control solutions (modified from k103329).

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 (sold separately), and three levels of control solution (Level II included, Level I and Level III sold separately). The system does not include a lancing device or lancets.

J. Substantial Equivalence Information:

1. Predicate device name(s):

DiaTrue Plus Blood Glucose Monitoring System

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

k103329

3. Comparison with predicate:

Similarities		
Item	Proposed Device DiaTrue Plus Blood Glucose Monitoring System	Predicate DiaTrue Plus Blood Glucose Monitoring System, K103329
Indications for use	Same	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.
Detection method	Same	Amperometric detection
Enzyme	Same	Glucose oxidase
Measurement range	Same	20-600 mg/dL
Sample volume (µL)	Same	1 µL
Maximum Altitude	Same	10000 ft
Control solution(s)	Same	Three levels available
Hematocrit range	Same	30-55%

Differences		
Item	Proposed Device DiaTrue Plus Blood Glucose Monitoring System	Predicate DiaTrue Plus Blood Glucose Monitoring System, K103329
Site	Fingertip and palm	Fingertip
Test Strip Storage Conditions	39°F to 86°F, between 20-75% RH	50°F to 77°F, below 75% RH
Control Solutions Storage Conditions	39°F to 86°F, between 20-75% RH	50°F to 77°F, below 75% RH

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

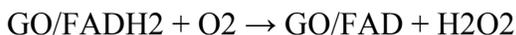
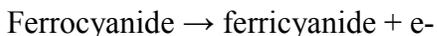
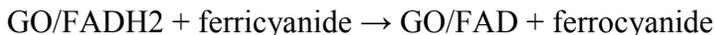
ISO 14971:2007. Medical devices-Application of risk management to medical devices.

ISO 15197. In vitro diagnostic test systems. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

CEN 13640. Stability Testing of In Vitro Diagnostic Reagents. (In Vitro Diagnostics).

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:*

As established in k103329

b. *Linearity/assay reportable range:*

As established in k103329

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

Traceability was established in k103329.

Stability

Test Strips:

Stability characteristics of the test strips were determined using real-time and accelerated studies, using closed vials. The testing protocol and acceptance criteria were reviewed and found to be adequate. When stored unopened at the recommended storage temperature of 39° F to 86°F (4-30°C) and between 20-75% relative humidity, 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 39 to 86 °C, and between 20-75% relative humidity.

The open-vial stability claim was established in k103329.

Control Solutions:

Stability characteristics of the control solutions were determined using real-time and accelerated studies, using closed 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 39° F to 86°F (4-30°C), and between 20-75% relative humidity. Once opened, the control solutions are stable for 3 months when stored at 39 to 86 °C.

The open-vial stability claim was established in k103329.

d. Detection limit:

As established in k103329

e. Analytical specificity:

As established in k103329

f. Assay cut-off:

As established in k103329

2. Comparison studies:

a. Method comparison:1

Testing on the fingertip was previously established in k103329.

The method comparison was performed with 120 participants, using 3 lots of test strips. Results from testing on the palm using the the DiaTrue Plus meter and DiaTrue Plus test strips were compared to YSI clinical chemistry analyzer. All testing was performed by health care professionals. Samples with concentrations between 33 and 533 mg/dL were used in the testing. 12 samples were altered, 6 at the low range (33, 34.2, 39.4, 41.6, 42.1, 47.1 mg/dL) and 6 at the high range (404, 419, 434, 491, 506, 533 mg/dL).

For glucose concentrations < 75 mg/dL:

	within ±5 mg/dL	within ±10 mg/dL	within ±15 mg/dL
Palm	13/20 (65.0%)	17/20 (85.0%)	20/20 (100.0%)

For glucose concentrations ≥ 75 mg/dL:

	within $\pm 5\%$	within $\pm 10\%$	within $\pm 15\%$	within $\pm 20\%$
Palm	46/100 (46.0%)	77/100 (77.0%)	92/100 (92.0%)	97/100 (97.0%)

The following is the linear relationship between the DiaTrue Plus Blood Glucose Monitoring System and the YSI clinical chemistry analyzer:

	Regression equation	Standard error	Slope (95%CI)	Intercept (95%CI)
Palm	Y = 0.9823X-2.2554, $R^2 = 0.9816$	14.3787	0.9578~1.0068	-7.1819~2.6711

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 performance studies:

Testing on the fingertip was previously established in k103329.

150 participants, ages 21 to 80 years, 83 male and 67 female, performed self-testing on the palm. Participants were given labeling in English and no other instruction or coaching. Results ranged from 63.7 to 378.0 mg/dL. Results were compared to a YSI clinical chemistry analyzer and are summarized below.

For glucose concentrations < 75 mg/dL:

	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Palm	6/20 (30.0%)	17/20 (85.0%)	20/20 (100.0%)

For glucose concentrations ≥ 75 mg/dL:

	within $\pm 5\%$	within $\pm 10\%$	within $\pm 15\%$	within $\pm 20\%$
Palm	53/130 (40.8%)	94/130 (72.3%)	119/130 (91.5%)	125/130 (96.2%)

Lot number	Regression equation	Standard error	Slope (95%CI)	Intercept (95%CI)
Test Strip Lot 1 Palm	$Y = 0.9481X + 2.5264$, $R^2 = 0.9756$	12.2174	0.9046~0.9917	-4.9959~10.0488
Test Strip Lot 2 Palm	$Y = 0.9698X - 3.3467$, $R^2 = 0.9819$	12.6835	0.9316~1.0080	-11.1345~4.4410
Test Strip Lot 3 Palm	$Y = 0.9624X + 1.8537$, $R^2 = 0.9708$	12.7575	0.9140~1.0109	-6.6305~10.3379
Total (3 lots of test strips) Palm	$Y = 0.9590X + 0.6193$, $R^2 = 0.9769$	12.5082	0.9351~0.9830	-3.7978~5.0365

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 2012, Diabetes Care, 2012, vol.35, no Supplement 1, S13. Table 3. .”

N. Instrument Name:

DiaTrue Plus Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes or No .

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes or No .

2. Software:

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

Yes 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 fingertip and palm 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) DiaLife Mini Data Management System User Study: 50 people were in the study with 27 men and 23 women, ages 21 – 80 years, with a variety of educational backgrounds. The study included the upload of the transfer software and transferring the data from the meters. The user study compared 30 data sets between the meter and the PC. They also

performed bench testing and showed that the software is still accurate when the meter rolls over, > 500 readings.

2) Hematocrit Study:

As established in k103329

3) Altitude study:

As established in k103329

4) Sample volume study:

As established in k103329

5) Temperature and humidity studies:

As established in k103329

6) Infection Control Studies:

As established in k103329

7) EMC testing:

As established in k103329

8) A readability assessment was conducted and the results demonstrated that the User Manual, test strip package insert and control solution package insert were each written at the 7th grade level.

9) Customer support is available Monday through Friday 9:00 am to 5:00 pm EST by calling 1-855-933-5246.

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.