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

A. 510(k) Number:

k100806

B. Purpose for Submission:

New device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative amperometric whole blood glucose oxidase

E. Applicant:

DELBio Incorporation

F. Proprietary and Established Names:

DiaCheck Premium Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345, Glucose test system

   21CFR 862.1660, Quality control material (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 - Quality Control Material (Assayed and Unassayed)

4. Panel:

   Chemistry 75

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   Diacheck Premium Blood Glucose Monitoring System:
   The Diacheck Premium Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples from the fingertips by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

   The Diacheck Premium Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The system is intended for self testing outside the body (in vitro diagnostic use). This system should not be used for the screening or diagnosis of diabetes or for testing neonates.

   Diacheck Premium Blood Glucose Test Strips:
   The Diacheck Premium Blood Glucose Test Strips are for use with the Diacheck Premium Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples from the fingertip. The test strip is intended for self testing outside the body (in vitro diagnostic use). This system should not be used for the screening or diagnosis of diabetes or for testing neonates.

   Diacheck Glucose Control Solution:
   The Diacheck Control solutions are intended for use with Diacheck Premium Blood Glucose Meter and Diacheck Premium Blood Glucose Test Strips as a quality control check to verify that the meter and test strips are working together properly and that the test is being performed correctly.

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:

   The Diacheck Premium test strips must be used with the Diacheck Premium Blood Glucose Meter

I. Device Description:

The DiaCheck Premium Blood Glucose Monitoring System consists of the DiaCheck Premium glucose meter, DiaCheck Premium blood glucose test strips, one bottle of control solution (Level I), carrying case and operator's manual. Additional control solutions sold as a set (Levels I and II) may be purchased separately. The labeling states that users should purchase auto-disabling, single use lancing devices,

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Arkray GLUCOCARD 01 Blood Glucose Monitoring System

2. Predicate 510(k) number(s):
   k073416

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indications for Use	Intended for use in the quantitative measurement of glucose with fresh capillary whole blood from the finger as an aid in monitoring the effectiveness of diabetes control program.	Same
Measurement range	20 to 600 mg/dL	Same
Test principle	Amperometric	Same
Enzyme	Glucose oxidase	Same

Differences		
Item	Device	Predicate
Prescription or OTC use and setting	Over the counter for single patient use	Over the Counter and Prescription use; for use on single or multiple patients
Sample type	Capillary from finger tip	Capillary from finger tip or palm

Differences		
Item	Device	Predicate
Sample volume	1 µL	0.3 µL
Memory capability	512 results	360 results
Power source	Two AAA batteries	One 3V Lithium CR2032 battery
Control Solution	Two levels available	Three levels available

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

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

L. Test Principle:

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 repeatability was evaluated with 3 lots of test strips and ten (10) glucose meters. Venous blood samples obtained from healthy adult volunteers were spiked or allowed to glycolyze in order to obtain five samples with glucose concentrations across the measuring range of the device. The samples were measured 10 times each, for a total of 100 individual measurements per sample. The results for each lot of test strips are summarized below:

Glucose Conc.	Lot 1		Glucose Conc.	Lot 2		Glucose Conc.	Lot 3	
Mean (mg/dL)	SD	CV (%)	Mean (mg/dL)	SD	CV (%)	Mean (mg/dL)	SD	CV (%)
59.1	3.8	6.4	57.3	4.4	7.7	57.1	4.4	7.7
102.9	4.1	4.0	100.2	2.8	2.8	99.6	3.0	3.0
149.1	5.9	4.0	152.1	3.8	2.5	152.4	4.2	2.8

246.6	6.6	2.7	245.6	7.4	3.0	247.8	7.3	2.9
396.1	9.5	2.4	400.1	11.1	2.8	400.0	12.3	3.1

The between day precision was evaluated with 3 lots of test strips and ten (10) glucose meters. Quality control material at three glucose concentrations was measured once a day for ten days, for a total of 100 measurements per control. The results for each lot of test strips are summarized below.

	Lot 1			Lot 2			Lot 3		
Quality Control	Mean (mg/dL)	SD	CV (%)	Mean (mg/dL)	SD	CV (%)	Mean (mg/dL)	SD	CV (%)
Low	57	4.3	7.5	52	4.2	8.1	56.2	4.2	7.5
Mid	101.9	3.5	3.5	106.8	3.7	3.4	104.1	3.4	3.2
High	304.9	8.5	2.8	313.2	9.2	3.0	306.1	8.9	2.9

b. Linearity/assay reportable range:

A linearity study was performed using venous blood samples spiked with glucose at eight (8) glucose concentrations, ranging from 17 to 661 mg/dL. Each specimen was tested in duplicate on ten different meters, with three different lots of test strips. The sponsor performed these studies using a version of the meter with the Hi and Lo glucose concentration flags disabled. All samples were also tested on the YSI 2300 analyzer to generate the expected values.

The results of meter readings vs. YSI values were compared using linear regression analysis and are summarized in the table below:

Strip Lot	**Slope**	**Intercept**	**R2**
A	1.006	-4.796	0.998
B	1.013	-4.969	0.999
C	0.998	-1.428	0.999

The results of the study support the sponsor's claim that the test system is linear from 20-600 mg/dL.

Results equal to or below 20 mg/dL are reported as "Lo" and results greater than or equal to 600 mg/dL reported as "Hi."

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

The DiaCheck Premium blood glucose monitoring system is traceable to the NIST SRM 917A reference material.

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:*

See linearity study

e. *Analytical specificity:*

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.

Interferant tested	**Concentration**
Acetaminophen	15 mg/dL
Ascorbic acid	3 mg/dL
Salicylic acid	30 mg/dL
Ibuprofen	12 mg/dL
Tetracycline	1.5 mg/dL
Tolazamide	8.4 mg/dL
Tolbutamide	16 mg/mL
Dopamine	0.1 mg/dL
Methyl-dopa	1.5 mg/dL
Creatinine	30 mg/dL

Urea	130 mg/dL
Bilirubin	10 mg/dL
Uric acid	9 mg/dL
Triglyceride	1500 mg/dL
Total Cholesterol	500 mg/dL
Levodopa	7 mg/dL
Glutathione	1.5 mmol/L
Gentisic Acid	2 mg/dL
Maltose	450 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.

Hematocrit Study

The effect of different hematocrit levels was evaluated with one test strip lot and 10 glucose meters and using blood samples at six glucose concentrations (20-50, 50-70, 110-130, 220-250, 350-380 and 520-550 mg/dL). The glucose samples were prepared from venous blood at five different hematocrit levels 25, 30, 45, 55, and 65%. Glucose results for each concentration and hematocrit level were compared to samples tested on the YSI reference method.

The data supports the sponsor's claim that hematocrit in the range of 30%-55% does not significantly interfere (more than ± 15%) with glucose measurements using the test system.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

System Accuracy Study

The sponsor conducted an accuracy study at three hospital sites. Trained professionals obtained 130 samples from diabetic and non-diabetic outpatient participants. The range of glucose values for the samples was 25-567 mg/dL. In order to obtain sufficient samples in the lowest and highest concentration intervals, 16 venous samples were obtained and either allowed to glycolyze to obtain low values or spiked with additional glucose. Samples that were <60 mg/dL and >430 mg/dL were contrived samples and samples between 65 to 430 mg/dL were natural capillary samples from the fingertip.

Testing was performed by one lab professional at each site and using 3 lots of test strips. All specimens were also evaluated by the YSI reference method. The results are summarized below:

For glucose concentrations ≤ 75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
19/28 (68%)	25/28 (89%)	28/28 (100%)

For glucose concentrations > 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
39/102 (38%)	69/102 (68%)	92/102 (90%)	101/102 (99%)

Linear regression analysis resulted in the following equation:

y= 1.02x + 4.05, r= 0.988

b. Matrix comparison:

Not applicable. Capillary whole blood is the only indicated sample 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):

User Performance Study
A study was conducted to demonstrate that untrained lay users can correctly perform a glucose test using the DiaCheck Premium test system and obtain accurate results. In all, 150 male and female subjects of varying demographics were recruited. Each subject was asked to perform a self test using only the provided English language labeling. A venous blood specimen from each subject was also obtained by a healthcare professional and tested on the YSI reference method.

The results are summarized in the tables below.

For glucose concentrations ≤ 75 mg/dL

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

For glucose concentrations > 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
52/147 (35%)	101/147 (69%)	128/147 (87%)	141/147 (96%)

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:
   The sponsor included the following expected values for non-diabetic normal glucose levels 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:

Diacheck Premium Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:
   Each test strip is single use and requires 1 uL sample volume of capillary blood.

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?
   Yes _____ or No ___X____

2. Software:
   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 only. The whole blood sample is applied directly to the test strip.

5. Calibration:

   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 is providing a one level of glucose control solution (Level M) with the starter kit for the device. A two level control set (Level M and Level H) is available for purchase separately. Recommendations on when to test the control materials are provided in the labeling. An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. Altitude:

   A study was conducted to evaluate the effect of altitude up to 9,000 feet on performance of the test system. Venous whole blood samples at six glucose concentrations ranging from 45-569 mg/dL were tested at sea level and 9,000 feet using three lots of test strips and ten meters. Each sample was also evaluated by the YSI method. At altitudes up to 9,000 feet, test results were within +/-10% of YSI values.

2. Test system operating conditions:

   Studies were performed using ten meters, three lots of test strips, and six venous whole blood samples with glucose concentrations spanning the range of the device. Testing was performed at various conditions in the claimed conditions 50-104°F (10-40°C) and at a relative humidity from 20-85% and results compared to the reference YSI. There were no significant differences in glucose concentrations across the temperature and humidity ranges tested. Results demonstrated that the test system can be used at temperatures from 50-104°F (10-40°C) and at a relative humidity from 20-85%.

3. 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.

4. 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.

5. EMC testing was evaluated and certified by Electronics Testing Center Taiwan and a letter of attestation was issued to the sponsor on March 20, 2009.

6. 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 300 cleaning and disinfection cycles designed to simulate 5 years of device use.

7. A sample volume study was performed to verify the test strip sample volume requirement of 1 µL. Three samples with glucose concentrations approximately 50, 150, and 300 mg/dL were evaluated with three lots of test strips with 5 different meters. Each of the three blood samples was applied to the strips at samples volumes 0.6, 0.7, 0.8, 0.9, 1.0, 1.2, and 1.5 µL. Protocols and acceptance criteria were provided and found to be acceptable. The sponsor concluded that sample volumes ≥ 0.8 µL produced accurate results and sample volumes <0.8 µL produced inaccurate results. The labeling provides instructions and graphics to assist the user in obtaining and applying an adequate sample volume.

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.