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

A. 510(k) Number:

k122307

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose from the finger

D. Type of Test:

Quantitative, amperometric assay, glucose oxidase

E. Applicant:

BioCare Corporation

F. Proprietary and Established Names:

DIAVUE Prudential Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1345, Glucose test system
   21 CFR 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

4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indications for Use below.

2. Indication(s) for use:
   DIAVUE Prudential Blood Glucose Monitoring System
   The DIAVUE Prudential Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use) by people with diabetes at home to monitor the effectiveness of diabetes control. It is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples (from finger). This system is intended to be used by a single person and should not be shared. It should not be used for the diagnosis of or screening for diabetes, or testing on neonates.

   DIAVUE Blood Glucose Test Strips
   The DIAVUE Blood Glucose Test Strips are to be used with the DIAVUE Prudential Blood Glucose Meter; it measures glucose in capillary whole blood taken rom a fingertip. It is for use outside of body (*in vitro diagnostic use*). It is intended fot lay use by people with diabetes and should only be usede by a single patient. This system should not be shared. They are not indicated for the diagnosis or screening of diabetes or for neonatal use.

   DIAVUE Control Solutions
   The DIAVUE Control Solutions are used with the DIAVUE Prudential Blood Glucose Meter and DIAVUE Blood Glucose Test Strips to indicate appropriate user technique and to indicate that the test strip and meter are functioning properly.

3. Special conditions for use statement(s):
   For Over the Counter use
   Not for use on neonates
   Not for the diagnosis of or screening for diabetes mellitus
   Not to be used for patients who are dehydrated, hypotensive, in shock, critically ill or in a hyperosmolar state

4. Special instrument requirements:
   DIAVUE Prudential Blood Glucose Meter

I. Device Description:

The DIAVUE Prudential Blood Glucose Monitoring System consists of the DIAVUE Prudential Blood Glucose Meter, DIAVUE Blood Glucose Test Strips and DIAVUE Control Solutions

The DIAVUE Prudential Glucose Monitoring System is based on an electrochemical biosensor technology (electrochemical) and the principle of capillary action. Capillary action at the end of the test strip draws the blood into the action chamber and the blood glucose result is displayed in 7 seconds.

The Diavue Control Solutions are aqueous based control materials available in 3 levels that are used to test the performance of the device. The target ranges are as follows: Level 1 35-65 mg/dL, Level 2 112-168 mg/dL, Level 3 224-336 mg/dL.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   URIGHT TD-4254 Blood Glucose Monitoring System

2. Predicate 510(k) number(s):
   K082482

3. Comparison with predicate:

Item	**Candidate Devices** DIAVUE Prudential Blood Glucose Monitoring System	**Predicate** URIGHT TD-4254 Blood Glucose Monitoring System (k082482)
Indications for use	The DIAVUE Prudential Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use) by people with diabetes at home to monitor the effectiveness of diabetes control. It is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples (from finger). This system is intended to be used by a single person and should not be shared. It should not be used for the diagnosis of, or screening for diabetes, or testing on neonates.	Same
Test Principle	Electrochemical biosensor with carbon electrodes that measures current produced by a chemical reaction	Same
Enzyme	Glucose oxidase	Same

Item	Candidate Devices DIAVUE Prudential Blood Glucose Monitoring System	Predicate URIGHT TD-4254 Blood Glucose Monitoring System (k082482)
Sample Type	Fresh capillary whole blood	Same
Sample Site	Fingertip	Same
Memory feature	450 tests	Same
Day average	7-, 14-, 21-, 28-, 60- and 90- day average glucose result	7-, 14-, 30- day average glucose result
Measuring time	7 sec	Same
Measurement range	20-600 mg/dL	Same
Sample Volume	0.7 μL	Same
Meter dimensions (mm)	90(L)x52(W)x15(H) mm	90(L)x52.4(W)x15.5(H) mm
Weight (g)	45.6 g	48.4
Test strip	DIAVUE Test Strip	U-RIGHT Blood Glucose Test Strip
Autocoding	Yes	No

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

- 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 – Applications of risk management to medical devices
- CLSI EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach
- CLSI EP7-A2: Interference testing in clinical chemistry; Approved Guideline – 2nd Edition

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 with the reagent of 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:
   Repeatability and intermediate precision studies were performed. For the repeatability studies, 10 replicates of each of 5 spiked venous whole blood glucose levels were analyzed using 10 meters and 3 lots of test strips. Repeatability results are summarized below.

	Test Strip Lot 1		
Samples	Mean	SD	% CV
Interval 1 30-50 mg/dL	38.8	1.64	4.23
Interval 2 51-110 mg/dL	78.5	2.33	2.97
Interval 3 111-150 mg/dL	117.6	2.66	2.26
Interval 4 151-250 mg/dL	201.3	6.08	3.02
Interval 5 251-400 mg/dL	303.9	8.70	2.86

	Test Strip Lot 2		
Samples	Mean	SD	% CV
Interval 1 30-50 mg/dL	38.8	1.52	3.91
Interval 2 51-110 mg/dL	79.4	2.22	2.80
Interval 3 111-150 mg/dL	118.3	2.97	2.51
Interval 4 151-250 mg/dL	208.6	5.59	2.68
Interval 5 251-400 mg/dL	302.7	9.00	2.97

	Test Strip Lot 3		
Samples	Mean	SD	% CV
Interval 1 30-50 mg/dL	39.1	1.58	4.06
Interval 2 51-110 mg/dL	80.1	2.02	2.53
Interval 3 111-150 mg/dL	120.2	3.10	2.58
Interval 4 151-250 mg/dL	204.4	6.85	3.35
Interval 5 251-400 mg/dL	299.9	7.23	2.41

An intermediate precision study was performed, consisting of 10 replicates per day, for 10 days using each of 3 levels of control solution. Each sample was tested using 10 meters and 3 lots of test strips**.** Results are summarized below.

	Test Strip Lot 1		
Samples	Mean	SD	% CV
Control Level 1 30-50 mg/dL	40.1	1.77	4.41
Control Level 2 110-150 mg/dL	129.6	3.62	2.80
Control Level 3 264-357 mg/dL	315.3	7.59	2.41

	Test Strip Lot 2		
Samples	Mean	SD	% CV
Control Level 1 30-50 mg/dL	39.6	1.51	4.18
Control Level 2 110-150 mg/dL	130.4	2.98	2.28
Control Level 3 264-357 mg/dL	312.9	6.81	2.18

	Test Strip Lot 3		
Samples	Mean	SD	% CV
Control Level 1 30-50 mg/dL	39.2	1.51	3.85
Control Level 2 110-150 mg/dL	128.9	3.50	2.71
Control Level 3 264-357 mg/dL	309.0	7.90	2.56

b. Linearity/assay reportable range:

Linearity was evaluated using 3 lots of test strips, 5 meters, and 10 venous whole blood samples with glucose levels ranging from 10-700 mg/dL, obtained by spiking pooled venous blood with a glucose solution. Each glucose level was analyzed 5 times over 3 test strip lots. Linear regression analysis for each test strip lot compared to the YSI resulted in:

$y = 0.9898x + 1.282$; $R^2 = 0.9988$ for Test Strip Lot 1
$y = 0.9996x + 2.998$; $R^2 = 0.9983$ for Test Strip Lot 2
$y = 0.9979x – 1.936$; $R^2 = 0.9986$ for Test Strip Lot 3

The claimed range of measurement for this device is 20 to 600 mg/dL. Data from bench studies and software verification studies were provided to demonstrate that if a sample is less than 20 mg/dL, the result is flagged by the meter as LO. If a sample result exceeds 600 mg/dL, the result is flagged by the meter as HI.

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

Traceability:

The Diavue Prudential Blood Glucose Monitoring System is traceable to the NIST SRM 917b reference material. The method comparison study was performed using the candidate device and YSI as the reference method (see Section M.2.a.).

Control Stability:

Diavue Control Solutions Level 1, Level 2 and Level 3 are available for use with this test system. The control solutions are not provided with the meter. The sponsor provided a protocol and acceptance criteria to verify the closed-vial stability (shelf life) and open vial stability of the control solutions. The stability protocols and acceptance criteria were reviewed and found acceptable. The sponsor claims a closed-vial (shelf life) of 24 months and open-vial stability of 3 months when stored at 36-86°F (2-30° C).

Control Value Assignment:

Values for each level of Diavue control solution are assigned by repeat analysis using 25 Diavue glucose test strips from one lot and 25 Diavue Prudential glucose meters. The mean, SD and CV are used to establish the ranges for each control solution level which are provided on the test strip vial label.

Test Strip Stability:

The sponsor provided a protocol and acceptance criteria to verify the closed-vial stability (shelf life) and open vial stability of the test strips. The stability protocols and acceptance criteria were reviewed and found to be acceptable. The sponsor claims a closed-vial (shelf life) of 24 months and open-vial stability of 6 months when stored at 39-104°F (4-40° C) and between 10% to 85% relative humidity.

d. Detection limit:

The reportable range is 20 to 600 mg/dL based on linearity studies above (section M.1.b.).

e. Analytical specificity:

The sponsor tested substances for interference using 1 lot of test strips (4-7 test strips per interferent level), 4 meters, and 2 levels of glucose (achieved by adjusting human venous blood glucose levels to 70 mg/dL and 150 mg/dL). Samples were then spiked with the following interfering substances. Each sample was analyzed 4 times. The labeling states that elevated concentration of acetaminophen (> 6.25 mg/dL), ascorbic acid (> 5 mg/dL), bilirubin (un-conjugated) (> 20 mg/dL), dopamine (> 1.25 mg/dL), glutathione reduced (> 46 mg/dL), levo-dopa (> 1.4 mg/dL), methyl-dopa (> 1.25 mg/dL), tolazamide (> 12.5 mg/dL), uric acid (> 10 mg/dL), galactose (> 250 mg/dL), mannose (> 250 mg/dL), triglycerides (> 3000 mg/dL), hemoglobin (> 100 mg/dL), and pralidoxime iodine (> 5 mg/dL) may affect test results. The following table lists the concentrations of each substance at which no significant interference (≤ 10%) was detected:

Test Substance	**Therapeutic/ Physiological Levels (mg/dL)**	**Test Levels (mg/dL)**
Acetylsalicylic Acid	2 to 10	50
Acyclovir	0.23 to 0.31	3.1
Allopurinol	0.5	5
Amitriptylline	0.012 to 0.025	0.25
Amoxicillin	0.55 to 1.1	11

Ampicillin	0.5	5
Salicylic acid	10-30	60
Atenolol	0.1 to 2.0	10
Bicarbonate	244	336
Cholic acid	0.7	6.0
Caffeine	0.3 to 1.5	10
Calcium	2.8 mM	5 mM
Chloride	108 mM	140 mM
Cholesterol	300	500
Chlonidine	0.0001 to 0.0002	2
Creatinine	1.7	30
Digoxin	0.0001 to 0.0002	0.16
Diphenhydramine	0.01 to 0.1	1.0
Enalapril	0.012 to 0.015	0.15
Ephendrine HCl	1.8	50
Erythromycin	0.2 to 2.0	20
Estrone	0.0011	0.1
Famotidine	0.008 to 0,013	0.13
Fluoxetine	0.08	0.8
Fructose	7.5	1000
Furosemide	0.1 to 0.3	2.0
Gentisic Acid	0.2 to 0.6	2.0
Glyburide	0.018 to 0.025	1.07
Ibuprofen	1 to 7	55
Isomalt	N/A	1000
Lacitol	N/A	1000
Lactose	< 0.5	1000
Lidocaine	0.15 to 0.16	6
Magnesium	1.1 mM	5 mM
Malitol	N/A	1000
Maltose	N/A	1000
Mannitol	0.0128	1000
Metaproterenol	0.0002 to 0.0013	1.81
Metformin HCl	0.5 to 4.0	50
Metoprolol	0.005 to 0.027	0.3
Naproxen	3 to 12	100
Nifedipine	0.017	0.17
Nortriptyline	0.005 to	0.15

	0.015	
Penicillin	1.2	12
Phenytoin	1 to 2	10
Piroxicam	0.3 to 0.5	5.0
Potassium	5.9 mM	10 mM
Sodium	135 to 145 mM	200 mM
Sorbitol	0.044	1000
Sulfamethoxazole	5 to 12	20
Sulfate	1 mM	5 mM
Terfenadine	0.00015 to 0.00045	0.45
Tetracycline	0.4	10
Theophylline	1.0 to 2.0	25
Tolbutamide	4.32 to 24	64
Total Protein	6000 to 8000	12000
Urea	38	600
Vancomycin	0.025	25
Verapamil	0.014 to 0.045	0.45
Vitamin E	0.5 to 2.0	20
Warfarin	0.1 to 1.0	2
Xylitol	N/A	1000
Xylose	N/A	1000

f. Assay cut-off:
Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:
Reference Method Comparison:
The sponsor performed a system accuracy evaluation comparing the DIAVUE Prudential BGMS to YSI. Healthcare professionals tested 180 capillary samples ranging in glucose concentration from 32 to 551 mg/dL, using 6 meters and 3 lots of test strips using the DIAVUE Prudential meter and the YSI (the reference method). Eight of the samples tested were glycolyzed or spiked to achieve concentrationss < 50 mg/dL and > 483 mg/dL. Results are summarized below.

For glucose concentrations <75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
14/16 (87.5%)	16/16 (100.0%)	16/16 (100.0%)

For glucose concentrations ≥ 75 mg/dL

within ± 5 %	Within ± 10 %	within ± 15 %	within ± 20 %
76/164 (46.3%)	160/164 (97.6%)	164/164 (100.0%)	164/164 (100.0%)

Linear Regression Analysis:

Comparison	N	Slope and y-intercept	R^2
DIAVUE Prudential vs. YSI	180	Y = 0.9871x + 3.6338	0.9914

b. Matrix comparison:
Not applicable. Capillary whole blood is the only indicated 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):
Lay-User Study:
The sponsor performed a lay-user study where accuracy of the device was tested using 172 fingerstick samples obtained by the lay-user. Participants, who were able to read the User's Manual in English, were instructed to read the manual and perform testing on the finger. A technician collected capillary blood for measurements on YSI. Samples in the study contained glucose concentrations that ranged from 49 to 470 mg/dL. Results are summarized below.

For glucose concentrations <75 mg/dL

within ± 5 mg/dL	**within ± 10 mg/dL**	**within ± 15 mg/dL**
13/24 (54.2%)	24/24 (100.0%)	24/24 (100.0%)

For glucose concentrations ≥75 mg/dL

Within ± 5 %	**within ± 10 %**	**within ± 15 %**	**within ± 20 %**
67/148 (45.3%)	142/148 (95.9%)	148/148 (100.0%)	148/148 (100.0%)

Linear Regression Analysis:

N	Slope and y-intercept	R^2
172	Y = 0.9899x - 2.069	0.9817

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

Time of day	Range, Non-diabetes
Before meals	Less than 100 mg/dL
After meals	Less than 140 mg/dL

The sponsor references: American Diabetes Association. Standards of Medical Care in Diabetes, Diabetes Care. 2012;33:S1-100.

N. Instrument Name:

DIAVUE Prudential Blood Glucose Meter

O. System Descriptions:

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

   Yes ____X____ or No _____

   The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

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. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:
   The meter is a non-coding meter, therefore no coding is required by the user.

6. Quality Control:
   The sponsor manufactures three levels of glucose control solution, Level 1, Level 2, and Level 3 to be used with the DIAVUE Prudential Blood Glucose Monitoring System. These DIAVUE Control Solutions must be purchased separately and are not provided with the device kits. Instructions for how to purchase the control solution are provided in the user manuals. To perform a control test the user is instructed to press the "M" button when the test strip and blood symbol appears on the screen. The "ctl" symbol will then appear on the display. An acceptable range for each control level is printed on the test strip vial label. If the control values fall outside these ranges, the user is referred to the user manual and customer support for problems and more information

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

1. The device is intended for single-patient use. Disinfection studies were performed on the DIAVUE Prudential meter by outside commercial laboratory testing services to determine the disinfection efficacy of the meter to the recommended cleaning and disinfection protocol, and its effectiveness in preventing the spread of bloodborne pathogens, particularly hepatitis B virus (HBV). Micro-Kill Disinfecting wipes (EPA Reg. No: 59894-10-37549) were validated, demonstrating complete inactivation of live virus for use with the meter. The sponsor also conducted robustness studies and demonstrated that there was no change in performance or in the external materials of the meter after 5,000 cleaning and disinfection cycles to simulate 5 years of use by lay-users. Each robustness cycle tested consisted of one pre-clean wipe and one disinfecting wipe.

2. The effect of different hematocrit levels was evaluated with 3 lots of test strips using 10 test strips at each of 6 concentration ranges of glucose (20-30, 50-80, 100-150, 200-250, 350-400, 550-600 mg/dL). The glucose samples were prepared from venous blood samples at 5 hematocrit levels at approximately 20, 30, 40, 50 and 60%. Each of the results were compared to the value obtained from the same plasma glucose concentration obtained by YSI. The data vs. YSI was reviewed and was found to be acceptable to support the claimed hct range of 20-60%.

3. The effect of altitude was evaluated at five whole blood samples with glucose concentrations ranging from 60 to 568 mg/dL, testing at sea level to 15,000 feet (4500 meters) above sea level. Each glucose concentration was measured 4 times at each altitude. The bias was calculated relative to YSI at sea level up to 15,000 feet. The

results demonstrate that the system meets the acceptance criteria for testing at altitudes up to 11,500 feet (3,500 meters) above sea level.

4. The sponsor performed temperature and humidity studies at the combined extremes of 10°C/RH: 10%, 40°C/RH: 10%, 10°C/RH: 85%, and 40°C/RH: 85%, with venous blood samples (66-300 mg/dL) that demonstrated that the DIAVUE Prudential meter can be used at temperatures of 50 to 104°F (10 to 40°C) and 10% to 85% relative humidity.

5. Insufficient sample studies were performed at volumes of 0.4 to 1.5µL on five meters and one test strip lot. Three glucose concentrations were tested ranging from approximately 40-330 mg/dL, as determined by the YSI. Appropriate sample volume was determined if the meter testing could start properly and if the meter results matched the YSI results. A blood volume ≥ 0.7 µL, the stated minimum sample volume requirement, met the criteria.

6. The sponsor provided a readability study and obtained Flesch-Kincaid Grade Level Scores of 7.3 for the test strip insert, 7.2 for the the DIAVUE Prudential User's Manual, and 7.2 for the control solution package insert.

7. The sponsor stated that they conformed to the following guidelines and provided the appropriate documentation to demonstrate compliance:

   - IEC/EN 61010-1: General Requirements Part 1. Safety requirements for electrical equipment for measurement, control, and laboratory use, 2001.
   - IEC/EN 61010-2-101: Particular Requiremnents for in vitro diagnostic medical equipment, 2002
   - EMC testing was evaluated and certified by SGS Taiwain Ltd. and a letter of attestation was issued to BioCare Corporation.

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.