

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

A. 510(k) Number:

k091102

B. Purpose for Submission:

New device

C. Measurand:

Whole blood glucose

D. Type of Test:

Whole blood glucose concentration through a quantitative amperometric assay (Glucose Oxidase)

E. Applicant:

ARKRAY Factory USA, Inc.

F. Proprietary and Established Names:

GLUCOCARD® Vital™ Blood Glucose Monitoring System
Assure Dose Control Solution

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1345, Blood Glucose Test System

21 CFR 862.1660, Quality Control Material (assayed and unassayed)

2. Classification:

Class II

Class I, reserved

3. Product codes:

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

CGA, Glucose Oxidase, Glucose

JJX, Single (specified) analyte controls (assayed and unassayed)

4. Panel:

75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):

Refer to indications for use below.

2. Indication(s) for use:

GLUCOCARD® Vital™ Blood Glucose Monitoring System:

The GLUCOCARD® Vital™ Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and palms. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. The GLUCOCARD® Vital™ Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

GLUCOCARD® Vital™ Blood Glucose Meter:

The GLUCOCARD® Vital™ Blood Glucose Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and palms. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

GLUCOCARD® Vital™ Blood Glucose Test Strips:

GLUCOCARD® Vital™ test strips are intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips and palms when used with the GLUCOCARD® Vital™ Blood Glucose Meter. Testing is done outside the body (In Vitro diagnostic use). They are indicated for use in home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

Assure Dose Control:

For use with GLUCOCARD® Vital™ Blood Glucose Meter and GLUCOCARD® Vital™ Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results. Control solutions are available in two levels – Level 1 (Normal) and Level 2 (High).

3. Special conditions for use statement(s):

- Not intended for diagnosis of diabetes mellitus
- For in vitro diagnostic use only
- Not intended for use on neonates
- Not for use on critically ill patients, dehydrated patients, patients in shock, or hyperosmolar patients
- Alternative site testing (AST) can be used only during steady-state blood glucose conditions. AST should ONLY be used in the following intervals:
 - In a pre-meal or fasting state (more than 2 hours since the last meal)
 - Two hours or more after taking insulin
 - Two hours or more after exercise

4. Special instrument requirements:

GLUCOCARD® Vital™ Blood Glucose Meter

I. Device Description:

The GLUCOCARD® Vital™ Blood Glucose Monitoring System consists of a meter, test strips, and two levels of control solutions. It uses biosensor technology to produce a quantitative glucose concentration from whole blood samples from the fingertip.

J. Substantial Equivalence Information:

1. Predicate device name(s):
PocketChem EZ Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
k063068
3. Comparison with predicate:

Similarities		
Item	New Device GLUCOCARD® Vital™	Predicate - k063068 Ferrara/PocketChem EZ
Indications for use	Same	As an aid to monitor the effectiveness of diabetes control
Anatomical Sites	Same	Fingertip, Palm
Maximum Altitude	Same	10,000 ft.
Operating Temperature Range	Same	50° F to 104° F
Operating Humidity Range	Same	20 – 80%

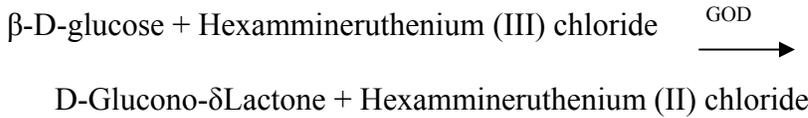
Differences		
Item	New Device GLUCOCARD® Vital™	Predicate - k063068 Ferrara/PocketChem EZ
Enzyme and Associated Reagents	Glucose Oxidase (<i>Aspergillus niger</i>) and Hexammineruthenium (III) chloride	Glucose Oxidase (<i>Aspergillus niger</i>)
Double Dosing Capability	No	Yes
Code Chip	No/autocoding	Required
Test Time	7 sec	10 Seconds
Hematocrit Range	33-52%	30 – 55%
Minimum Sample Volume	0.5 µL	1.0 µL

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

- CLSI EP-07-A2, Interference Testing in Clinical Chemistry, 2005
- CLSI EP-6A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline, 2003.
- 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 sample (whole blood) is drawn by capillary action at the tip of the test strip. Glucose in the sample reacts with glucose oxidase (GOD) and Hexammineruthenium (III) chloride in the test strip. This produces Hexammineruthenium (II) chloride. Hexammineruthenium (II) chloride is produced in proportion to the glucose concentration of the blood sample. Oxidation of the Hexammineruthenium (II) chloride produces an electric current. The meter converts the current to the glucose concentration and displays it as the test result:



M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Within-Day precision testing was performed using fresh venous whole blood obtained from several non-diabetic volunteers and adjusted to a pO₂ of 60 to 80 mm Hg and hematocrit of 42%. The whole blood was spiked to obtain 5 glucose concentrations ranging from 44.1 – 306 mg/dL. Within-Day precision tests consisted of 10 measurements of each of the five spiked whole blood glucose samples using 10 meters for each sample for a total of 500 measurements. The within-run precision for all meters and concentrations tested was as follows:

Glucose Conc. (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
44.1	1.28	2.90
83.0	2.43	2.70
131.3	4.10	2.84
181.9	5.65	2.87
306.0	8.24	2.51

The Day to Day precision testing was performed using three glucose levels of control solutions; ten individual users performed this evaluation using ten meters over a period of 10 days, for a total of 100 measurements per level. This was repeated with three lots of test strips.

Lot A			
Level	Low	Mid	High
Mean	38.0 mg/dL	100.2 mg/dL	313.6 mg/dL
Standard Deviation	0.51	1.26	9.39
Coefficient of Variation (%)	1.35	1.26	2.99
Lot B			
Level	Low	Mid	High

Mean	38.1 mg/dL	101.9 mg/dL	313.6 mg/dL
Standard Deviation	0.38	1.96	8.82
Coefficient of Variation (%)	1.01	1.93	2.81

Lot C			
Level	Low	Mid	High
Mean	38.2 mg/dL	100.9 mg/dL	320.4 mg/dL
Standard Deviation	0.44	1.41	8.80
Coefficient of Variation (%)	1.14	1.40	2.75

b. Linearity/assay reportable range:

The measuring range of the device is 20-600 mg/dL. A linearity study was conducted consistent with CLSI EP6-A using venous whole blood collected in a 10 mL vacuum sample tube. Glucose was adjusted to 11 concentration levels ranging from 13.5 to 699.4 mg/dL (The Lo and Hi detection was disabled for this testing). Ten GLUCOCARD® Vital™ meter measurements were taken at each glucose concentration. The linear regression line for three lots was: $y = 0.9976x + 0.1441$, $r^2 = 0.997$.

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

The control solutions used in this device have been previously cleared (k063068). Shelf life studies show that the unopened test strips have a twenty-four month life-span and a three month shelf-life once a vial of strips is opened. The recommended storage temperature is 39° F - 86° F (4° C - 30° C).

d. Detection limit:

The detection limit is 20 mg/dL. See linearity/assay reportable range above.

e. Analytical specificity:

The sponsor evaluated the interference from different concentrations of the substances listed below. Three glucose levels were tested for each interferent including a low (50 – 80 mg/dL range), medium (120 – 160 mg/dL range), and high (302 – 382 mg/dL range). A total of 15 readings were taken for each glucose level and concentration of interferent (5 meters per each of 3 test strip lots). Studies demonstrated that all the interfering substances listed below did not significantly interfere with the glucose readings.

- Acetaminophen up to 20 mg/dL
- Acetyl-Salicylic Acid up to 65 mg/dL
- Ascorbic acid up to 6 mg/dL
- Bilirubin (unconjugated) up to 33 mg/dL
- Bilirubin (conjugated) up to 67 mg/dL
- Cholesterol up to 500 mg/dL
- Creatinine up to 5.0 mg/dL

Dopamine up to 0.09 mg/dL
Ephedrine up to 0.06 mg/dL
Fructose up to 30 mg/dL
Galactose up to 60 mg/dL
Gentisic Acid up to 1.8 mg/dL
Glutathione up to 3.00 mg/dL
Hemoglobin up to 1470 mg/dL
Ibuprofen up to 50 mg/dL
L-DOPA up to 13 mg/dL
Lactose up to 30 mg/dL
Maltose up to 450 mg/dL
Maltotetrose up to 450 mg/dL
Maltotoriose up to 240 mg/dL
Mannitol up to 800 mg/dL
Mannose up to 16 mg/dL
Methyl-L-Dopa up to 1.5 mg/dL
Salicylic Acid up to 100 mg/dL
Sorbitol up to 10 mg/dL
Tetracycline up to 1.5 mg/dL
Tolazamide up to 70 mg/dL
Triglyceride up to 3300 mg/dL
Tolbutamide up to 64 mg/dL
Urea up to 280 mg/dL
Uric Acid up to 23 mg/dL
Warfarin up to 1.0 mg/dL
Xylitol up to 50 mg/dL
Xylose up to 80 mg/dL

Altitude Study

A study was conducted to evaluate the effect of altitude on the GLUCOCARD® Vital™ Glucose Meter using the new glucose strips. Venous blood collected from a donor was allowed to undergo glycolysis at room temperature to lower the endogenous glucose to approximately 40 mg/dL. The sample was separated into 4 aliquots and spiked with glucose to levels of approximately 60, 125, 300 and 480 mg/dL. These glucose values were confirmed with the YSI glucose analyzer. The tests were performed at approximately 900 feet and at 10,500 feet. At each altitude, venous blood at each of the 4 levels of glucose was tested on the same test strip lot with 10 replicates. The meter readings obtained at 10,500 feet were compared to the meter readings at sea level and the % bias was determined at each level. Results recovered within 3.3% when compared to the readings near sea level. The labeling states that the GLUCOCARD® Vital™-V1 strips can be used at elevations up to 10,000 feet above sea level.

Hematocrit Study

The sponsor performed hematocrit studies comparing the GLUCOCARD® Vital™ result at various hematocrit levels across the glucose measuring range to the normal

hematocrit level and to a reference analyzer. Hematocrit levels tested were 30, 33, 35, 37, 40, 42, 45, 50, 51, 52, 53, and 55% and glucose levels tested were approximately 40, 120, 250, and 450 mg/dL. Testing was performed on two lots of test strips. Based on the comparisons to the reference analyzer and to normal hematocrit (42%), the results for hematocrit levels between 33-52% showed a bias of less than ± 15 mg/dL at glucose concentrations less than 75mg/dL or less than $\pm 15\%$ at glucose concentrations ≥ 75 mg/dL.

- f. *Assay cut-off:*
Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

A method comparison study was performed with 120 capillary fingerstick samples where the participants tested themselves. Testing was performed on 3 lots of V1 strips using GLUCOCARD™Vital meters. The distribution of gender, diabetes type, age, and education level were as follows. Note: one participant was found to be hypoglycemic and was removed from the study for medical reasons. Results from this participant were not included in the study.

Gender	Number	% of Total
Male	70	58
Female	50	42

Diabetes	Number	% of Total
Type 1	47	39
Type 2	68	57
Not specified	5	4

Age Group	Number	% of Total
18 – 30	9	7.5
31 – 40	14	11.7
41 – 50	26	21.7
51 – 60	24	20.0
61 – 70	26	21.7
71 – 82	21	17.5

The range of concentrations of 119 samples was 47 – 522 mg/dL by the reference method. The linear regression line for the accuracy study was, $y = 1.02x - 7.7$, $r^2 = 0.99$. The accuracy for GLUCOCARD™Vital vs. YSI in the format of ISO 15197 is given below.

Fingerstick accuracy for glucose concentrations < 75 mg/dL:
(GLUCOCARD™Vital vs. YSI)

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
4/6 (67%)	5/6 (83%)	6/6 (100%)

Fingerstick accuracy for glucose concentrations ≥ 75 mg/dL:
(GLUCOCARD™Vital vs. YSI)

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
53/113 (47%)	92/113 (81%)	108/113 (96%)	111/113 (98%)

The sponsor also evaluated the accuracy of samples taken from the palm where 117 of the participants tested themselves. The results in comparison to the YSI in ISO 15197 format are tabulated below.

Palm accuracy for glucose concentrations < 75 mg/dL:
(GLUCOCARD™Vital vs. YSI)

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
5/6 (83%)	6/6 (100%)	6/6 (100%)

Palm accuracy for glucose concentrations ≥ 75 mg/dL:
(GLUCOCARD™Vital vs. YSI)

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
53/111 (48%)	91/111 (82%)	103/111 (93%)	109/111 (98%)

b. *Matrix comparison:*

Not applicable. Only capillary whole blood samples can be used with this meter.

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):*

The minimum recommended sample volume for this system is 0.5 µL. To validate performance the sponsor performed testing at sample volumes of 0.2 µL – 10 µL. The results demonstrated that their sample volume claim is supported.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Expected values for people without diabetes¹:

Fasting: <100 mg/dL

1 – 2 hours after meals < 140 mg/dL

¹Joslin Diabetes Center: *Goals for Blood Glucose Control*, 2008. www.joslin.org

N. Instrument Name:

GLUCOCARD™ Vital 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 each additional reading.

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:

This device is intended to be used with capillary whole blood from the finger and palm only. Since the whole blood sample is applied directly to the test strip, there are no special handling or storage issues.

5. Calibration:

No calibration is required from the user. The meter accommodates auto-coding, in that each strip is designed and manufactured to code the meter appropriately when the strip is inserted.

6. Quality Control:

Two levels of control are supplied with the device. Users are instructed to test control solutions when the meter is first used in order to verify that they can use the meter correctly. In addition they are instructed to run a control when a new vial of test strips is opened, when they suspect the meter or strips are not working correctly, if test results appear to be abnormally high or low, or are not consistent with the patient's symptoms, if the meter is dropped, to check their technique, if the test strip bottle had been left open or stored outside its recommended temperature range, and each time the batteries are changed.

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

The sponsor performed a readability assessment of the labeling and states that the lay user instructions in the user manual, strip insert, and control insert are at 8.0, 7.5, and 7.5 grade level, respectively.

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.