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

A. 510(k) Number:

k170064

B. Purpose for Submission:

New Device

C. Measurand:

Glucose in fresh capillary whole blood obtained from the fingertip and palm

D. Type of Test:

Quantitative, amperometric method, glucose oxidase

E. Applicant:

Arkray Factory USA, Inc.

F. Proprietary and Established Names:

GLUCOCARD W Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345, glucose test system

2. Classification:

   Class II

3. Product code:

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

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indictation(s) for use below.

2. Indication(s) for use:

   The GLUCOCARD W Blood Glucose Monitoring System is comprised of GLUCOCARD W Blood Glucose Meter, GLUCOCARD W Blood Glucose Test Strips and Assure® Control–Control Solution. The GLUCOCARD W Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip or palm. Testing is done outside the body (in vitro diagnostic use). It is intended for use at home by persons with diabetes, as an aid in monitoring the effectiveness of a diabetes control program.

   The GLUCOCARD W Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. This system is not for use in diagnosis or screening of diabetes mellitus, nor for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

3. Special conditions for use statement(s):

   The labeling has the following limitation statements:
   - For over-the-counter use only
   - In vitro diagnostic use
   - Do not use the GLUCOCARD W Blood Glucose Monitoring System for the diagnosis of, or screening for diabetes
   - The meter and lancing device are for single-pateint use and should not be shared even with family members. Do not use on multiple patients.
   - Do not use results from alternative site samples to calibrate continuos glucose monitoring systems (CGMS) or for insulin dose calculations.
   - Do not use the GLUCOCARD W Blood Glucose Monitoring System to test neonates. It has not been validated for neonatal use.
   - Do not use if you are in shock, dehydrated or hyperosmolar
   - Do not use at altitudes higher than 10,335 ft (3,150 m)
   - Extremes in hematocrit may affect test results. Blood outside the hematocrit range of 20–70% may cause false readings.
   - Severe dehydration (excessive water loss) may cause false low results. If you believe you are suffering from dehydration, consult your healthcare professional right away.
   - Patients undergoing oxygen therapy may yield false results.
   - Inaccurate results may occur in severely hypotensive individuals or patients in shock.
   - Inaccurate low results may occur for individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.

- Not for use in the critically ill population population. This meter should not be used to test critically ill patients.
- Patients undergoing oxygen therapy may yield inaccurate results
- Patients taking high doses of Vitamin C (ascorbic acid; blood levels of 4 mg/dL or higher) may get inaccurate results with this system.
- Do not test the blood sample from palm when glucose is changing rapidly (senarios: after drinking, after meal, after exercise).

4. Special instrument requirements:

   GLUCOCARD W Blood Glucose Meter

I. Device Description:

The GLUCOCARD W Blood Glucose Monitoring System consists of a battery-powered GLUCOCARD W Blood Glucose Meter, disposable GLUCOCARD W Blood Glucose Test Strips and Assure® Control–Control Solution (Levels 1, 2, and 3). Level 2 is provided in the device kit and all levels are available for purchase separately. The device has the capability to communicate with an external PC using a commercially available USB cable.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   GLUCOCARD® Vital™ Blood Glucose Monitoring System

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

   k091102

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indications for Use	Intended for use at home by persons with diabetes, as an aid in monitoring the effectiveness of a diabetes control program.	Same
Use Setting	At home for single patient use	Same
Measurement Method	Amperometric	Same
Measuring Range	20 to 600 mg/dL	Same
Enzyme	Glucose oxidase	Same
Sample Type	Fresh Capillary Whole Blood	Same
Sample Site	Fingertip and palm	Same

Similarities		
Item	Device	Predicate
Calibration	Automatic coded calibration	Same
Minimum Sample Volume	0.5 µL	Same
Test Time	7 seconds	Same

Differences		
Item	Device	Predicate
Hematocrit range	20-70%	33-52%
Hematocrit Correction function	Yes	No
Communication Function	Yes, micro USB Port	Yes-2.5 mm jack PC Interface Port
Memory Capacity	500 test results	250 test results
Sample Auto Detection Function	Automatically detects if a sample is whole blood or control solution	Cannot detect differences between whole blood and control solution
Flag for low blood sugar	Yes	No
Dimensions	84 mm x 50 mm x 17.6 mm	80 mm x 46 mm x 16 mm
Weight	47 g	39 g
Control solutions	Three levels	Two levels

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

CLSI EP06-A "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach"; Approved Guideline (2003)
CLSI EP07-A2 "Interference Testing in Clinical Chemistry"; Approved Guideline-Second Edition (2005)

CLSI EP09-A2 "Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline"

CLSI EP25-A "Evaluation of Stability of In Vitro Diagnostic Reagents"; Approved Guideline (2009)

L. Test Principle:

The GLUCOCARD S Blood Glucose Monitoring System operates on the electrochemical detection of the reaction of glucose with the enzyme glucose oxidase. Glucose in the blood reacts with the reagent in the test strip, and this produces a small electric current. The strength of this current is proportional to the concentration of glucose in the blood. The meter measures this current and calculates the blood glucose concentration that is then displayed on the meter.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The sponsor performed within-run precision studies using venous whole blood samples spiked with 5 different concentration ranges of glucose; 30-50, 51-110, 111-150, 151-250, and 251-400 mg/dL. Each glucose concentration range was analyzed in replicates of 10 on ten different GLUCOCARD W meters, using 3 different test strip lots in a single day, for a total of 300 tests for each glucose level. Results of the testing are summarized below:

Glucose Level (mg/dL)	Lot	Mean (mg/dL)	n	SD (mg/dL)	%CV
30 to 50	A	42.9	300	1.8	4.2
	B	44.2		1.9	4.2
	C	40.5		1.4	3.6
51 to 110	A	72.0	300	1.7	2.4
	B	74.1		2.0	2.7
	C	72.3		2.3	3.2
111 to 150	A	144.0	300	3.7	2.6
	B	149.3		4.9	3.3
	C	149.5		5.1	3.4
151 to 250	A	227.0	300	4.8	2.1
	B	234.0		6.5	2.8
	C	235.5		7.7	3.3
251 to 400	A	369.0	300	8.8	2.4
	B	379.6		15.8	4.2
	C	385.4		11.6	3.0

Intermediate (day to day) precision was evaluated by measuring 5 levels of glucose control solutions (30-50 mg/dL; 51-110 mg/dL, 111-150 mg/dL, 151-250, and 251-400) over 10 days with 3 test strip lots using ten meters. For each level, 10 replicates were tested per each lot of test for a total of 300 tests for each glucose level. Results of the testing are summarized below:

Glucose Level (mg/dL)	Lot	Mean (mg/dL)	n	SD (mg/dL)	%CV
30 to 50	A	44.1	300	0.8	1.9
	B	40.5		0.9	2.1
	C	43.6		0.9	2.0
51 to 110	A	87.6	300	1.7	2.1
	B	72.3		1.6	1.8
	C	87.4		1.5	1.8
111 to 150	A	150.5	300	2.9	2.1
	B	149.5		2.6	1.7
	C	150.4		2.7	1.8
151 to 250	A	211.0	300	4.2	2.1
	B	235.5		4.5	2.1
	C	211.4		4.1	2.0
251 to 400	A	381.7	300	10.3	2.8
	B	385.4		8.4	2.2
	C	389.6		9.4	2.4

b. Linearity/assay reportable range:

Linearity testing was performed using venous whole blood samples. A total of eleven different concentrations of glucose using three lots of test strips and ten meters were tested. Samples with the following glucose concentrations (mg/dL) were prepared and measured: 17.2, 80.9, 132.0, 201.9, 274.1, 339.2, 414.0, 491.5, 571.6, 630.5, and 666.2 mg/dL. Glucose values were compared to those obtained from a laboratory based comparator method (YSI 2300 analyzer)). Each concentration level was tested 30 times. The resulting regression equation based on all measurements is provided below:

Lot 1: $y = 1.021x - 2.494$; $R^2 = 0.999$
Lot 2: $y = 0.990 - 1.794$; $R^2 = 0.999$
Lot 3: $y = 1.022x - 3.088$; $R^2 = 0.999$

The results of the study support the sponsor's claimed glucose measuring range of 20 to 600 mg/dL.

The GLUCOCARD W Blood Glucose Meter displays results between 20 and 600 mg/dL. The message 'HI' appears when results are greater than 600 mg/dL and the message 'Lo' appears when a test result is less than 20 mg/dL. The 'Hi/Lo' error message feature was validated using blood glucose samples outside the measuring range to demonstrate that the feature functions as intended.

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

Traceability:
The system is traceable to the NIST SRM #917c glucose reference material.

Test Strip Stability:
Test Strip stability was assessed through accelerated and real-time open vial and closed vial studies. Protocols and acceptance criteria were reviewed and found to be acceptable. The manufacturer claims closed vial stability of 24 months and open vial stability of 6 months when stored at 34–86°F, 10-90% relative humidity. The labeling instructs the users not to freeze the test strips.

d. *Detection limit:*

The reportable range of the device is 20 to 600 mg/dL. See linearity study in Section M1b above.

e. *Analytical specificity:*

Interference studies were carried out by evaluating 27 endogenous and exogenous substances in venous blood samples with 3 different levels of glucose concentrations; approximately 60 mg/dL, 120 mg/dL, and 250 mg/dL as measured by a laboratory based comparator method (YSI 2300 analyzer). Each sample was divided into a test pool containing samples spiked with interferent and untreated samples. Ten meters and three different test strip lots were used to test 30 replicates per test sample and compared to control test results obtained from the meter. No interference was defined by the sponsor as ≤ 10% at each glucose level. Results are presented in the table below:

Interfering substance	**Highest Concentration with no Significant Interference**
Acetaminophen	20 mg/dL
Ascorbic acid	4 mg/dL
Bilirubin Unconjugated	40 mg/dL
Bilirubin Conjugated	50 mg/dL
Cholesterol	500 mg/dL
Creatinine	10 mg/dL
L-DOPA	5 mg/dL
L-Dopamine	20 mg/dL
EDTA	180 mg/dL
Galactose	15 mg/dL
Gentisic acid	700 mg/dL
Glutathione	92 mg/dL
Heparin	500 IU/mL
Hemoglobin	20.8 g/dL

Interfering substance	Highest Concentration with no Significant Interference
Ibuprofen	50 mg/dL
Icodextrin	1094.4 mg/dL
Maltose	5,000 mg/dL
Mannitol	100 mg/dL
Methyl-L-dopa	1000 mg/dL
Salicylic acid	60 mg/dL
Sodium chloride	1015 mg/dL
Tolazamide	40 mg/dL
Tolbutamide	100 mg/dL
Triglyceride	3,000 mg/dL
Uric acid	24 mg/dL
Xylitol	0.2 mg/dL
Xylose	200 mg/dL

The sponsor has the following limitation in their labeling:

"Patients taking high doses of Vitamin C (ascorbic acid; blood levels of 4 mg/dL or higher) may get inaccurate results with this system."

f. Assay cut-off:
Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

See M.3.c below.

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):*

To assess the performance of the GLUCOCARD W Blood Glucose Monitoring System in the hands of the intended users, the sponsor performed a study at 3 sites with a total of 300 English speaking participants. Three hundred participants collected and tested samples from their own fingertip and 240 participants collected and tested samples from their palm. The participants used only the labeling materials to inform testing. A total of seven lots of test strips and GLUCOCARD W Blood Glucose Meters were used. Results were analyzed by comparing the blood glucose results obtained by the lay users with the GLUCOCARD W Blood Glucose Monitoring System against results obtained with a laboratory based comparator method (YSI 2300 analyzer). The glucose concentrations in the samples ranged from 49-467 and 60-468 mg/dL for fingerstick and palm respectively, as measured by the laboratory based comparator method. The results are summarized below:

Fingerstick vs. laboratory based comparator method:

Glucose Concentrations < 75 mg/dL		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
13/13 (100%)	13/13 (100%)	13/13 (100%)

Glucose Concentrations ≥ 75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
183/287 (63.8%)	265/287 (92.3%)	284/287 (99%)	286/287(99.7%)

Combined Glucose Concentrations Across the Measuring Range			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
191/300 (63.7%)	278/300 (92.7%)	297/300 (99%)	299/300 (99.7%)

Palm vs. laboratory based comparator method:

Glucose Concentrations < 75 mg/dL		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
6/9 (66.7%)	9/9 (100%)	9/9 (100%)

Glucose Concentrations ≥ 75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
130/231 (56.3%)	204/231 (88.3%)	224/231 (97%)	229/231 (99.1%)

Combined Glucose Concentrations Across the Measuring Range			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
134/240 (55.8%)	213/240 (88.8%)	233/240 (97.1%)	238/240 (99.2%)

Linear Regression Analysis:
Fingerstick vs. laboratory based comparator method: Linear regression:
$y = 1.02x - 4.56$; $r2 = 0.99$; $N = 300$

Palm vs. laboratory based comparator method: Linear regression:
y = 1.02x – 2.05; r2 = 99; N = 240

The readability assessment using a Flesch-Kincaid analysis for the GLUCOCARD W A questionnaire designed to evaluate the ease of use of the device and the clarity of the English language labeling was completed by the subjects that participated in the lay-user study.. The responses to the Instructions for Use Questionnaire met the sponsor's acceptance criteria, with lay users demonstrating acceptable levels of comprehension of the labeling. Labeling was assessed and determined to be at an 8th grade reading level or less. The meter manual states that customer service is available (24 hours a day, 7 days a week) by calling 1-800-566-8558.

Accuracy of the GLUCOCARD W System vs. laboratory based comparator method at extreme glucose values:

To assess the performance of the system with extreme glucose concentrations the sponsor altered 100 capillary whole blood samples, by spiking or allowing samples to glycolyse, to achieve glucose concentrations below 80 mg/dL and above 250 mg/dL. Fifty samples were allowed to glycolyze to achieve glucose concentrations of 19.5 to 78.5 mg/dL and 50 samples were altered to achieve glucose concentrations of 259 to 568 mg/dL, as measured by a laboratory based comparator method (YSI 2300 analyzer). Results were analyzed by comparing the blood glucose results obtained on the GLUCOCARD W Blood Glucose Monitoring System against results obtained with a laboratory comparator method (YSI 2300 analyzer). The data is summarized below:

Glucose Concentrations ≤ 80 mg/dL		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
44/50 (88%)	49/50 (98%)	50/50 (100%)

Glucose Concentrations ≥ 250 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
27/50 (54%)	41/50 (82%)	50/50 (100%)	50/50 (100%)

4. Clinical cut-off**:**

   Not applicable**.**

5. Expected values/Reference range:

   The range of a normal fasting blood glucose level for non-diabetic adults is less than 100. Two (2) hours after a meal, the range of a normal blood glucose level for non-diabetic adults is less than 140 mg/dL (7.8 mmol/L).
   American Diabetes Association. "Standards of Medical Care in Diabetes - 2017." Diabetes Care. January 2017; 40(1):S12

N. Instrument Name:

GLUCOCARD W 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 ___X____ or No _____

   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. The user directly applies the blood sample to the test strip as they are collected.

4. Specimen Sampling and Handling:

   The system is intended to be used with capillary whole blood from the finger and palm. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   There is no calibration required by the user for the GLUCOCARD W blood glucose meters. The meters are automatically coded by information on the test strips.

6. Quality Control:

   Three levels of glucose control solutions are available with this system, but only Level 2 is provided with the kit; all glucose solutions are also sold separately. The device automatically detects whether a sample is capillary blood or control solution. 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 and to contact customer support if the control result falls outside these ranges.

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

1. Hematocrit Study:
   To evaluate the effect of hematocrit on the Glucocard W Blood Glucose Monitoring System, venous whole blood samples were adjusted to hematocrit levels of 20%, 35%, 30%, 35%, 40%, 42%, 45%, 50%, 55%, 60%, 65% and 70%. Each hematocrit level was tested at five glucose concentration intervals (45, 67, 134, 200, 336 mg/dL). A single glucose determination for each sample aliquot was made using three different lots of test strips tested with ten different meters and compared to values obtained using a laboratory analyzer (YSI 2300 analyzer). The percent biases relative to laboratory based comparator method demonstrated acceptable performance across the claimed hematocrit range of 20-70%.

2. Altitude Study:
   An altitude study was conducted at two different locations at two different altitudes (Hsinchu City at sea level-377 feet and Mt. Hehuan at 10,335 feet). At each altitude, venous blood samples at six glucose concentrations (47.8, 72.2, 147.7, 242.1, 388.0, and 475.3 mg/dL) were tested using three lots of test strips and ten meters. The results obtained using the GLUCOCARD W Blood Glucose monitoring system were compared to results obtained using a laboratory based comparator method (YSI 2300 analyzer). The results demonstrate acceptable bias to the laboratory based comparator method to support the claims in the labeling that altitudes up to 10,335 feet (3150 meters) have no significant effect on blood glucose measurements on the GLUCOCARD W Blood Glucose Monitoring System.

3. Sample Volume:
   The sponsor performed a study to support the claimed minimum sample volume for the GLUCOCARD W Blood Glucose Monitoring System. Blood samples with three levels of glucose (60, 110, and 225 mg/dL) were tested at six sample volumes (0.1, 0.3, 0.5, 1.0, 5.0, and 10.0 μL) using 3 test strip lots and 10 meters. The values obtained using the GLUCOCARD W Blood Glucose Monitoring System were compared to values obtained using the laboratory based comparator method (YSI 2300 analyzer). The meter has an error feature (E13) that is displayed when not enough blood is added to the test strip. This feature was validated and was shown to function as intended. Results support the claimed minimum sample volume of 0.5 μL.

4. Temperature and Humidity Studies:
   The sponsor performed operating conditions studies using venous blood samples at three glucose concentrations (67, 134, and 336 mg/dL) to evaluate temperatures from 5°C to 45°C and relative humidity (RH) from 10 % to 90 % RH. Four temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, high temperature/low humidity, and high temperature/high humidity. The results from the GLUCOCARD W Blood Glucose Monitoring System were compared to the laboratory based comparator method (YSI 2300) and percent bias calculated. Results demonstrated that glucose measurements on the GLUCOCARD W Blood Glucose Monitoring System were not significantly affected by the tested conditions. The results support the claims in the labeling that the system can be used in temperature conditions of 46-104˚F (8°C to 40°C) and relative humidity between 10 to 90%.

5. Sample Perturbation:
   The sponsor performed sample perturbation studies using venous whole blood samples comparing meter readings to results from the laboratory-based comparator method (YSI 2300 analyzer). Results were obtained without perturbation of the test strip and various methods of perturbation. The results support that the performance of GLUCOCARD W Blood Glucose Monitoring System is acceptable when samples are perturbed.

6. Intermittent Sampling:
   The sponsor assessed the performance of the device when intermittent sampling occurs using venous whole blood samples comparing meter readings to results from the laboratory based comparator method (YSI). Results were obtained by adding samples to the test strip that were less than the required volume followed by a second sample application to the test strip The results support that the GLUCOCARD W Blood Glucose Monitoring System does not provide blood glucose values when samples are intermittently applied. The labeling indicates that the user should not reapply or apply more sample after the testing has begun..

7. Testing with Used Test Strips:
   The sponsor assessed the performance of the device when used test strips were inserted into the meter using capillary blood and control solutions. Each test resulted in an error code. The results support that the performance of the GLUCOCARD W Blood Glucose Monitoring System is acceptable when used test strips are inserted into the meter.

8. Infection Control and Robustness Studies:
   The GLUCOCARD W Blood Glucose Monitoring System is intended for single patient home use only. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of viral hepatitis B virus (HBV) with the chosen disinfectant, Clorox Healthcare Bleach Germicidal Wipes (EPA Reg. No: 67619-12). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 160 cleaning and disinfection cycles designed to simulate 3 years of single-patient use (approximately one cleaning and disinfection cycle per week). Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

9. EMC Testing:
   The sponsor provided appropriate documentation certifying that electromagnetic (EMC) testing was performed and the GLUCOCARD W Blood Glucose Monitoring System were found to be compliant.

10. This device was cleared after the FDA issued final guidance documents for prescription use blood glucose monitoring systems (BGMS) and over-the-counter use blood glucose monitoring systems (SMBG). However, the recommendations in the guidance documents were not followed for this device since the studies were conducted prior to the finalization of the guidance documents.

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.