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

A. 510(k) Number:

k142035

B. Purpose for Submission:

Modified device - Test strip's electrode print pattern, capillary gate size, upper logo layers and outer shape have been modified).

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, Amperometric method (Glucose Oxidase)

E. Applicant:

ARKRAY Factory USA, Inc.

F. Proprietary and Established Names:

GLUCOCARD 01-mini Blood Glucose Monitoring System

ReliOn Micro Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
CGA – Glucose oxidase, glucose	Class II	21 CFR § 862.1345	75-Chemistry
NBW – system, test, blood glucose, over the counter	Class II	21 CFR § 862.1345	75-Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

GLUCOCARD 01-mini Blood Glucose Monitoring System

The GLUCOCARD 01-mini Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, or palm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home by persons with diabetes as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. It is intended for single patient use and should not be shared with other individuals.

The GLUCOCARD 01 SENSOR Plus Blood Glucose Test Strips are intended to be used with the GLUCOCARD 01-mini Blood Glucose Meter for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, or palm.

ReliOn Micro Blood Glucose Monitoring System

The ReliOn Micro Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, or palm. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home by persons with diabetes as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. It is intended for single patient use and should not be shared with other individuals.

The ReliOn Confirm Plus Blood Glucose Test Strips are intended to be used with the ReliOn Micro Blood Glucose Meters for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, or palm.

3. Special conditions for use statement(s):

For over-the-counter use only.
For single-patient use only.
For use with fresh capillary whole blood samples drawn from the fingertip and palm only.
Not for neonatal use, not for screening or diagnosis of diabetes mellitus.
This meter should not be used to test critically ill patients.
Patients undergoing oxygen therapy may yield false results.
Palm testing (Alternative site testing, AST) should not be used to calibrate continuous glucose monitors (CGMs) or for insulin dose calculations. Palm testing (Alternative site testing, AST) should only be used during steady-state blood glucose conditions.

4. Special instrument requirements:

   GLUCOCARD 01-mini Blood Glucose Meter
   ReliOn Micro Blood Glucose Meter

I. Device Description:

The GLUCOCARD 01-mini is a blood glucose monitoring system for self-testing consisting of a battery-powered meter, disposable test strip ("SENSOR"), and control solutions. It utilizes biosensor technology for the quantitative determination of glucose concentrations in capillary blood samples.

The current system is identical to the predicate device GLUCOCARD 01-mini blood monitoring system cleared in k082417 except that the manufacturing process for the GLUCOCARD 01 SENSOR Blood Glucose Test Strip has been modified to allow for more efficient manufacturing production. The modifications to the test strip did not require any changes to meter hardware, software or other components of the test system.

The GLUCOCARD 01-mini Blood Glucose Monitoring System contains the following components:
GLUCOCARD 01-mini Blood Glucose Meter
GLUCOCARD 01 SENSOR Plus Blood Glucose Test Strips
01 SENSOR Control Solutions (3 Levels, cleared under k073416)
Multi-Lancet Device (Class I exempt), for use with disposable lancets

The system is also marketed under the ReliOn brand name with a different outer design and materials. The ReliOn System contains the following components:

ReliOn Micro Blood Glucose Meter
ReliOn Confirm Plus Blood Glucose Test Strips
ReliOn Confirm/Micro Control Solutions (3 Levels, cleared under k073416)
ReliOn Lancing Device (Class I exempt), for use with disposable lancet

J. Substantial Equivalence Information:

1. Predicate device name(s):

   GLUCOCARD 01-mini Blood Glucose Monitoring System

2. Predicate K number(s):

   k082417

3. Comparison with predicate:

Item	**Predicate Device** GLUCOCARD 01-mini Blood Glucose Monitoring System (k082417)	**Candidate Device** GLUCOCARD 01-mini **and ReliOn Micro** Blood Glucose Monitoring Systems (k142035)
Similarities		
Intended Use/Indications for Use	For the quantitative measurement of glucose in fresh capillary whole blood samples by persons with diabetes as an aid to monitor the effectiveness of diabetes control. For Over-the-counter (OTC) use.	Same
Strip Chemistry	Glucose oxidase and hexaammineruthenium (III) chloride	Same
Calibration	Automatic coded calibration Same	Same
Sample volume	0.3 µL	Same
Test Time	7 seconds	Same
Test Range (mg/dL)	20-600	Same
Hematocrit Range	30-54%	30-55%
Test Strip Open Use Life	3 months after opening	3 months after opening
System Operating Range – Temperature	50°F to 104°F (10°C to 40°C)	Same
System Operating Range - Humidity	20-80%	Same
Maximum Altitude	10,000 feet above sea level	Same
Controls Solution(s)	Three levels available	Same
Differences		
Test Strip	Electrode print pattern, capillary gate size, upper logo layers and outer shape	Different

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

ISO 14971: Medical devices – Application of risk management of medical devices

L. Test Principle:

The sample (whole blood) is drawn into the tip of the test strip by capillary action. Glucose in the sample reacts with glucose oxidase and hexaammineruthenium (III) chloride in the test strip. This produces hexaammineruthenium (II) chloride. Hexaammineruthenium (II) chloride is produced in proportion to the glucose concentration of the blood sample. Oxidation of the hexaammineruthenium (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):

The GLUCOCARD 01-mini Blood Glucose Monitoring System and ReliOn Micro Blood Glucose Monitoring System are the same system under two brand names. The only difference between the two systems is the outer case design and material. As such, separate performance testing was not necessary for each brand, a common name of "meter" and "strips" is therefore referred to in the below described performance studies.

1. Analytical performance:

   a. *Precision/Reproducibility:*

      Within-run precision was evaluated using venous blood samples collected in sodium heparin tubes. The pooled sample was glycolyzed overnight, oxygenated to 60 - 80 mmHg pO2 and adjusted to a hematocrit of 41-44%. The whole blood pool was divided into aliquots and spiked with concentrated glucose solution to achieve five different glucose concentrations, 30-50, 51-110, 111-150, 151-250, and 251-400 mg/dL. Each sample was measured in 10 replicates with 10 meters using each of the three lots of test strips (N=100/lot). Reference glucose concentrations were determined with a YSI Model 2300. Results are summarized below:

Within-run precision for glucose:

Strip Lot	Mean (mg/dL)	SD	% CV
1	40.0	1.7	4.1%
	83.5	2.9	3.5%
	131	4.4	3.3%
	223	8.1	3.6%
	349	8.8	2.5%
Strip Lot	Mean (mg/dL)	SD	% CV
2	44.2	2.5	5.6%
	79.7	3.4	4.3%
	129	4.4	3.4%
	231	9.7	4.2%
	351	7.7	2.2%
Strip Lot	Mean (mg/dL)	SD	% CV
3	44.8	2.3	5.2%
	80.0	3.2	4.0%
	128	4.6	3.6%
	228	7.8	3.4%
	349	8.7	2.5%

Between-day precision was evaluated using three levels of control solutions. Each sample was tested in singlet on ten meters using each of the three lots of test strips on 10 different days (N=100/Lot). Results are summarized below:

Between-day precision for glucose:

Strip Lot	Mean (mg/dL)	SD	CV%
1	47.4	2.1	4.5
	148	6.3	4.3
	410	14.7	3.6
2	47.5	1.6	3.4
	146	4.0	2.8
	409	16.9	4.1
3	47.6	1.6	2.9
	147	4.5	3.0
	415	17.4	4.2

b. Linearity/assay reportable range:

A fresh venous whole blood pool was split into two fractions with glucose

concentrations adjusted to create high (800 mg/dL) and low (10mg/dL) pools. These high and low pools were combined in various volume ratios to produce 15 test samples with glucose concentrations ranging from 10 – 750 mg/dL. The YSI reference concentrations at each level are: 13, 23, 43, 74, 95, 123, 204, 263, 333, 406, 500, 520, 567, 685, 764 mg/dL. Each sample was tested in singlicate using 10 meters and 3 lots of test strips. The meter was configured to allow the reporting of results outside the 'LO' and 'HI' limits (i.e. below 20 mg/dL and above 600 mg/dL). Lot specific meter values were plotted against the YSI reference values in the liner regression analysis (N=150). The result of the regression analysis is summarized in the below table:

Strip Lot /Meter	Slope	95% CI slope	Intercept	95% CI intercept	R^2
Lot 1	1.06	1.05 to 1.07	-6.251	-10.08 to -2.42	0.998
Lot 2	1.05	1.04 to 1.06	-7.965	-12.13 to -3.80	0.998
Lot 3	1.05	1.04 to 1.06	-8.125	-12.10 to -4.15	0.998
Combined	1.05	1.05 to 1.06	-7.45	-9.76 to -5.14	0.998

Based on these results, the sponsor claims a measuring range of 20-600 mg/dL for the proposed glucose monitoring system.

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

Traceability:

Traceable to NIST SRM 917c

Stability:

Test Strip Stability:
The sponsor provided real-time and accelerated studies to verify the closed- and open- vial stability of the test strips. The stability studies were reviewed and found to be acceptable. The closed-vial claim is 18 months when stored at of 18 months at 1-30 °C (34-86 °F) and 20-80% relative humidity. The open-vial stability claim is 3 months when stored at 1-30 °C (34-86 °F) and 20-80% relative humidity.

Control Solution:
The control solutions were previously cleared and stability and value assignment was previously established in k073416. The names of the control solution levels have been changed from L, N and H to L1, L2 and L3.

When stored at 34-86°F (1-30°C), unopened controls have an 18-month shelf life and are stable for 3 months after opening.

d. Detection limit:

See linearity study above.

e. Analytical specificity:

Interference

Interference studies were conducted in accordance with CLSI EP7-A2. Stock interferent solutions were prepared and spiked in aliquots of the low (100 mg/dL) and high glucose (300 mg/dL) whole blood pools to achieve final concentrations listed in the following table. "Untreated" control samples were spiked with the carrier solvent only. The glucose concentration of each test sample was determined with five meters using 3 lots of strips. The highest concentration for each substance that did not show interference, as defined by the sponsor, is tabulated below.

With the exception of pO_2, all other substances tested did not interfere with glucose measurements based upon the sponsor's definition of significant interferences (bias > ± 10% compared to un-spiked samples of glucose ≥ 75 mg/dL, or ≥ ± 10 mg/dL for samples with glucose concentrations < 75 mg/dL). The sponsor has the following limitations in their labeling: "Patients undergoing oxygen therapy may yield false results".

Substance	Level (mg/dL)	Substance	Level (mg/dL)
Acetaminophe	20	Maltotetraose	450
Acetylsalicylic	65	Maltotriose	240
Ascorbic acid	6	Mannitol	800
Bilirubin (conjugated)	30	Mannose	16
Bilirubin (unconjugated)	40	Methyl-L-DOPA	1.5
Cholesterol	500	Oxygen (pO_2)	100mm Hg
Creatinine	5	Pralidoxime	2056
L-DOPA	13	Salicylic acid	100
L-Dopamine	0.09	Tetracycline	4.0
Ephedrine	0.5	Tolazamide	10
Fructose	100	Tolbutamide	64
Galactose	100	Triglyceride	3000

Substance	Level (mg/dL)		Substance	Level (mg/dL)
Gentisic acid	10		Urea	600
Glutathione	3		Uric acid	25
Hemoglobin	735		Warfarin	10
Ibuprofen	50		Xylitol	0.2
Lactose	30		Xylose	200
Maltose	450			

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Trained Health Care Practitioners collected fingerstick, palm, and reference samples from study participants. Fingerstick, and palm samples were tested in singlicate using one of the three different glucose reagent strip lots. Reference glucose values were measured using the YSI method. The results are summarized in the tables below:

Professional User Fingerstick Glucose < 75 mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
24	18 of 24 (75.0%)	23 of 24 (95.8%)	23 of 24 (95.8%)

Professional User Finger Stick Glucose ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
198	111 of 198 (56.1%)	170 of 198(85.9%)	195 of 198 (98.5 %)	198 of 198 (100.0%)

Liner Regression between professional user finger stick and YSI:
Y=1.00X-2.61, N=222

Professional User Palm Glucose < 75 mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
7	6 of 7 (85.7%)	7 of 7 (100.0%)	7 of 7 (100.0%)

Professional User Palm Glucose ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
138	76 of 138 (59.6%)	108 of 138 (78.3%)	132 of 138 (95.7 %)	135 of 138 (97.8%)

Liner regression between professional user palm and YSI:
Y=1.05X-4.87, N=145

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 study was performed to compare the lay user self-test results and the YSI method. The study was performed in one clinical site in US with 148 subjects with type 1 or type 2 diabetes, age 20-86. All subjects performed fingerstick tests and palm tests; the results were compared to the YSI laboratory reference results from fingerstick blood. Each sample was tested in singlicate using one of the three lots of test strips.

The range of glucose values for the finger stick samples was 43-558 mg/dL measured by YSI. Linear regressions analysis results are summarized below:

Finger Stick Glucose < 75 mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
7	3 of 7 (42.9%)	7 of 7 (100.0%)	7 of 7 (100.0%)

Finger Stick Glucose ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
141	78 of 141 (55.3%)	117 of 141 (83.0%)	135 of 141 (95.7%)	140 of 141 (99.3%)

Palm Glucose < 75 mg/dL

Number of test results	Within ± 5 mg	Within ± 10 mg	Within ± 15 mg
7	5 of 7 (71.4%)	7 of 7 (100%)	7 of 7 (100%)

Palm Glucose ≧ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
141	71 of 141 (50.4%)	115 of 141 (81.6%)	133 of 141 (94.3%)	138 of 141 (97.9%)

Regressions between lay user's results and the YSI method:

Tester	Linear regressions	N
Lay user-finger stick	Y=1.01X-1.48	148
Lay user-palm	Y=1.04X-2.28	148

The participants were also 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.

Additionally, Flesch-Kincaid readability assessment was conducted and the results showed that the labeling (User Guide, test strip package insert and control solution package insert) were written at or lower than the 8th grade level.

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

   Expected blood glucose results were cited from the literature[1] and presented in the labeling as follows:

   Fasting and before meals <100 mg/dL
   1-2 hours after meals <140 mg/dL

   [1] American Diabetes Association Standards of Care, 2013

N. Instrument Name:

GLUCOCARD™ 01-Mini Blood Glucose Meter
ReliOn Micro Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and requires a sample volume of 0.6 uL.

   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. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   The glucose test 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:

   The meter is automatically coded. No calibration is required.

6. Quality Control:

   The sponsor manufactures three levels of glucose control solution, L1, L2, and L3 to be used with the GLUCOCARD™ 01-Mini Blood Glucose Monitoring System and the ReliOn Micro Blood Glucose Monitoring System. The L2 Control is included only in the System Kit for the GLUCOCARD™ 01-Mini Blood Glucose Monitoring System. Otherwise, these control solutions must be purchased separately. Instructions for how to purchase the control solution are provided in the user manuals. 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 assistance.

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

1. Sample volume study
   Venous whole blood was collected and prepared to establish glucose levels of approximately 50, 130 and 300 mg/dL. Sample volumes ranging from 0.15 µL to 10 µL were tested using 3 lots of strips and five meters. The sponsor defined acceptance criteria as bias of <10 mg/dL (for glucose concentrations < 75 mg/dL) or 10% (glucose concentrations >=75 mg/dL) for the various sample volumes tested in reference to control volume of 1 µL. Based on the results, the sponsor concluded that the proposed device provides accurate results with sample volumes as low as 0.3 µL.

2. Altitude study
   An altitude study was conducted to evaluate the effect of altitude up to 10,000 feet on performance of the blood glucose monitoring system. Venous whole blood samples at four glucose concentrations approximately 60, 150, 300, and 450 mg/dL were tested on one lot of test strips. Each sample was also evaluated by the YSI method. The results met the sponsor's acceptance criteria and demonstrated that the performance of the Blood Glucose Monitoring System is not affected by altitude up to 10,000 feet.

3. Hematocrit study:
   The effect of hematocrit on the performance of the meter and test strip was evaluated. Eight hematocrit levels (25-60%) each at 9 glucose concentrations (30.2 - 425.8 mg/dL) were tested using three lots of test strips and ten meters. Sample bias was calculated relative to the YSI reference method. The results

support the sponsor's claim that the system is accurate in hematocrit range of 30-55%.

4. Test system operating conditions:
   Temperature and humidity operating conditions were evaluated for temperatures ranging from 10°C to 40°C and relative humidity range from 20% to 80% including extreme combinations of temperature and humidity, e.g. lowest humidity with lowest and highest temperature and highest humidity with lowest and highest temperature. Protocols and acceptance criteria were provided and found to be acceptable.

5. EMC Testing:
   The sponsor provided documentation certifying that acceptable electromagnetic testing (EMC) had been performed.

6. Software documentation:
   The software documentation was reviewed and found to be acceptable.

7. Infection control studies:
   The devices are intended for single–patient use. Disinfection efficacy studies were performed using constituent surface materials of the GLUCOCARD 01-Mini meter, the ReliOn Micro Blood Glucose Meters by an outside commercial testing lab demonstrating complete inactivation of duck hepatitis B Virus (DHBV) with the chosen disinfectant, Clorox 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 416 cleaning and disinfection cycles, using Clorox Germicidal Wipes, to simulate cleaning twice a week over 4 years of single-patient use. Labeling has been reviewed for adequate instructions in validated cleaning and disinfection procedures.

8. Customer service is available 24 hours/day, 365 days a year. Toll free phone number is 1-800-566-8558 (GLUCOCARD™ 01-Mini) or 1-855-776-0662 (ReliOn Micro).

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.