1. Administrative Information

Applicant's Name and Address	ARKRAY Factory, Inc. 1480 Koji, Konan-cho Koka-shi, Shiga 520-3306 Japan Establishment Registration # 3003422726
Contact Person	Wendy J. Kivens, Ph.D., RAC (US) Regulatory Affairs Project Manager
Phone	952-646-3142
Fax	952-646-3230
Email	kivensw@arkrayusa.com
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2. Device Information

Device

Trade Name	GLUCOCARD® W Blood Glucose Monitoring System
Classification Name	System, Test, Blood Glucose, Over The Counter
Common Name	Blood Glucose Monitoring System
Product Code	NBW
Classification Panel	75 – Clinical Chemistry
Device Classification	21 CFR § 862.1345
510(k) Number	K170064

3. Predicate Device Information

Predicate Device Name	Predicate Device 510(k) Number
GLUCOCARD® Vital™ Blood Glucose Monitoring System	K091102

4. Device Description

The GLUCOCARD® W Blood Glucose Monitoring System is designed to quantitatively determine glucose concentrations in fresh capillary whole blood samples. 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). The GLUCOCARD® W Blood Glucose Monitoring System utilizes biosensor technology for the quantitative determination of glucose concentrations in capillary blood samples. Although capillary blood samples are used for measurement, the results displayed on the GLUCOCARD® W Blood Glucose Monitoring System are equivalent to plasma glucose levels.

The biosensor (GLUCOCARD® W Blood Glucose Test Strips) 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 your glucose level.

5. Indications for Use

The GLUCOCARD W Blood Glucose Monitoring System is comprised of GLUCOCARD W Blood Glucose Meter and GLUCOCARD W Blood Glucose Test Strips.

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).

6. Substantial Equivalence Information

The GLUCOCARD® W Blood Glucose Monitoring System is substantially equivalent to the GLUCOCARD® Vital Blood Glucose Monitoring System. Below is a table that provides a comparison between the GLUCOCARD® W Blood Glucose Monitoring System and its predicate device.

Similarities and Differences Table

COMPONENT/ CHARACTERISTIC	PROPOSED	PREDICATE
Blood Glucose Monitoring System		
510(k) Number	K170064	K091102
Monitoring System	GLUCOCARD® W Blood Glucose Monitoring System	GLUCOCARD® Vital™ Blood Glucose Monitoring System
Intended Use and Indications for Use	The GLUCOCARD W Blood Glucose Monitoring System is comprised of GLUCOCARD W Blood Glucose Meter and GLUCOCARD W Blood Glucose Test Strip. 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).	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. 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.
Measurement Method	Amperometric	Amperometric
Result Range	20 to 600 mg/dL	20 to 600 mg/dL

COMPONENT/ CHARACTERISTIC	PROPOSED	PREDICATE
Sample Type	Fresh Capillary Whole Blood[1]	Fresh Capillary Whole Blood[1]
Calibration Reference	Plasma referenced	Plasma referenced
Sample Application	Apply blood to end, capillary fill	Apply blood to end, capillary fill
Blood Source	Fingertip, palm	Fingertip, palm
Calibration Curve	Automatic coded calibration	Automatic coded calibration
Operating Temperature Range	46°F to 104°F 8°C to 40°C	50°F to 104°F 10°C to 40°C
Temperature Compensation	Automatic compensation using built-in thermosensor	Automatic compensation using built-in thermosensor
Operating Humidity Range	10% to 90% Relative Humidity (No condensation)	20% to 80% Relative Humidity (No condensation)
Maximum Altitude	10,335 ft. (3,150 m)	10,000 ft. (3,048 m)
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
Minimum Sample Volume	0.5 µL	0.5 µL
Test Time	7 Seconds	7 Seconds
Power On	Insert Test Strip into Meter	Insert Test Strip into Meter
Auto Power Off	Two minutes after last User operation (five minutes when waiting for blood application)	Two minutes after last user action
Sample Auto Detection Function	Automatically detects if a sample is whole blood or control solution	Cannot detect differences between whole blood and control solution
Average Calculations	7, 14, 30, 60, 90 days	14, 30 days
Flag for Low Blood Sugar	Yes	No

[1] Although whole blood samples are used for measurement, displayed results are equivalent to plasma glucose levels.

COMPONENT/ CHARACTERISTIC	PROPOSED	PREDICATE
Validated Cleaning and Disinfection Instructions	Yes	No
Buttons and Function	Three Button	Three Button
Dimensions	84 mm x 50 mm x 17.6 mm	80 mm x 46 mm x 16 mm
Weight	47 g	39 g
Batteries	1 x 3-volt lithium battery (CR2032)	1 x 3-volt lithium battery (CR2032)
Chemistry	Glucose Oxidase (*Aspergillus sp.*) and Hexaammineruthenium (III) chloride	Glucose Oxidase (*Aspergillus niger* sourced) and Hexaammineruthenium (III) chloride
Test Strip Size	29.45 x 5.5 x 0.80 mm	29.45 x 5.5 x 0.80 mm
Test Strip Color	White substrate/green dielectric	White substrate/green dielectric
Test Strip Calibration Codes	Three	Three
Storage Temperature	1°C to 30°C	4°C to 30°C
Shelf-Life	24 months	24 months
Open Bottle Shelf-Life	6 months after bottle opening	3 months after bottle opening
Container	Molecular sieve desiccant lined plastic vial/bottle/pot	Molecular sieve desiccant lined plastic vial/bottle/pot

7. Summary of Performance Testing

Performance testing on the proposed GLUCOCARD® W Blood Glucose Monitoring System demonstrated that the device meets the performance requirements for its intended use.

INFECTION CONTROL STUDIES

The GLUCOCARD® W Blood Glucose Monitoring System is intended for single patient use only. Cleaning and Disinfection efficacy was performed on the constituent surface meter materials demonstrating complete inactivation of hepatitis B virus with the chosen disinfecting agent, Clorox Healthcare™ Bleach Germicidal Wipes (EPA #67619-12).

ROBUSTNESS/DURABILITY

Robustness studies were performed by ARKRAY to demonstrate that there was no change in the performance or the external materials of the meter after 160 cleaning and disinfection cycles (representing weekly cleaning and disinfection for three years, the expected lifetime of the GLUCOCARD® W Blood Glucose Meter) with Clorox Healthcare™ Bleach Germicidal Wipes.

PRECISION

Within-run precision was performed using venous whole blood samples spiked with glucose to five levels. For within-run precision evaluation, samples were tested ten times with each of three lots of single test strips with ten meters for a total of 1,500 GLUCOCARD® W Blood Glucose Test Strips tested (n=500 per each test strip lot and 300 per each glucose level). Results are summarized in the table below.

Within-Run Precision Results

Glucose Level (mg/dL)	Test Strip Lot	Mean mg/dL	SD mg/dL	95% CI mg/dL	% CV
30 - 50	1	42.9	1.8	1.6 to 2.1	4.2%
	2	44.2	1.9	1.7 to 2.2	4.2%
	3	40.5	1.4	1.3 to 1.7	3.6%
51 - 110	1	72.0	1.7	1.5 to 2.0	2.4%
	2	74.1	2.0	1.8 to 2.4	2.7%
	3	72.3	2.3	2.0 to 2.7	3.2%
111 - 150	1	144.0	3.7	3.3 to 4.3	2.6%
	2	149.3	4.9	4.4 to 5.9	3.3%
	3	149.5	5.1	4.5 to 6.2	3.4%
151 - 250	1	227.0	4.8	4.2 to 5.6	2.1%
	2	234.0	6.5	5.8 to 7.8	2.8%
	3	235.5	7.7	6.8 to 9.6	3.3%
251 - 400	1	369.0	8.8	7.7 to 10.2	2.4%
	2	379.6	15.8	14.0 to 18.3	4.2%
	3	385.4	11.6	10.3 to 13.8	3.0%

The intermediate precision evaluation was performed with five levels of glucose control solutions. Users conducted testing over ten days using ten GLUCOCARD® W Blood Glucose Meters. Ten replicates of each control solution level were tested per GLUCOCARD® W Blood Glucose Test Strips lot. A total of three lots of GLUCOCARD® W Blood Glucose Test Strips were tested.

For intermediate precision evaluation, there were a total of 1,500 GLUCOCARD® W Blood Glucose Test Strips tested (n=500 per each test strip lot and 300 per each glucose level). Results are summarized in the table below.

Intermediate Precision Results

Glucose Level (mg/dL)	Test Strip Lot	Mean (mg/dL)	SD (mg/dL)	95% CI mg/dL	% CV
30 - 50	1	41.3	0.8	0.7 to 1.0	1.9%
	2	44.1	0.9	0.8 to 1.2	2.1%
	3	43.6	0.9	0.8 to 1.1	2.0%
	All Lots	43.0	1.5	1.4 to 1.7	3.5%
51 - 110	1	81.7	1.7	1.5 to 2.1	2.1%
	2	87.6	1.6	1.4 to 2.1	1.8%
	3	87.4	1.5	1.4 to 1.9	1.8%
	All Lots	85.6	3.2	3.0 to 3.5	3.7%
111 - 150	1	140.4	2.9	2.6 to 3.5	2.1%
	2	150.5	2.6	2.3 to 3.4	1.7%
	3	150.4	2.7	2.4 to 3.5	1.8%
	All Lots	147.1	5.5	5.1 to 6.0	3.7%
151 - 250	1	196.0	4.2	3.7 to 5.3	2.1%
	2	211.0	4.5	3.8 to 6.7	2.1%
	3	211.4	4.1	3.6 to 5.8	2.0%
	All Lots	206.1	8.3	7.7 to 9.3	4.0%
251 - 400	1	363.7	10.3	8.8 to 14.6	2.8%
	2	381.7	8.4	6.9 to 13.0	2.2%
	3	389.6	9.4	8.1 to 13.2	2.4%
	All Lots	378.3	14.3	13.2 to 16.9	3.8%

LINEARITY

The claimed measuring range for this device is 20–600 mg/dL.

Linearity was evaluated using venous whole blood samples spiked with glucose to eleven levels. The glucose concentration of each test sample was determined with ten GLUCOCARD® W Blood Glucose Meters. The test protocol was executed with three lots of the GLUCOCARD® W Blood Glucose Test Strips. For linearity evaluation, there were a total of 330 GLUCOCARD® W Blood Glucose Test Strips tested.

The values from the GLUCOCARD® W Blood Glucose Monitoring System were compared with those obtained from the YSI comparator. The results from the regression analyses are summarized below.

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

The results of the linearity study support the GLUCOCARD® W Blood Glucose Monitoring System claimed glucose measurement range of 20–600 mg/dL. The meter displays "Lo" with glucose values below 20 mg/dL, and "Hi" with glucose values over 600 mg/dL. The "Lo" and "Hi" functions were validated and demonstrated to function as intended.

METHOD COMPARISON/USER EVALUATION

To assess the performance of the GLUCOCARD® W Blood Glucose Monitoring System in the using a finger-stick as the sampling site in the hands of lay-users, ARKRAY performed studies with 300 lay-user Participants. Participants were provided with labeling for the GLUCOCARD® W Blood Glucose Monitoring System. No other training or prompting was provided to the Participants. When ready, the Participants performed their own testing without assistance. Results were analyzed by comparing blood glucose results from finger-stick samples using the GLUCOCARD® W Blood Glucose Monitoring System obtained by the Participants against the reference method value (YSI 2300).

Finger-stick data on the GLUCOCARD® W Blood Glucose Monitoring System from Participants with Diabetes testing on their palm were evaluated against 2016 FDA Guidance: *Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use* and found to be acceptable. The results are summarized the table below.

Finger-Stick Data Accuracy

Difference range between the true blood glucose level and the GLUCOCARD® W Blood Glucose Meter result.	**Within ± 5%**	**Within ± 10%**	**Within ± 15%**	**Within ± 20%**
The percent (and number) of meter results that match true blood glucose level within x%	63.7% (191/300)	92.7% (278/300)	99.0% (297/300)	99.7% (299/300)

To assess the performance of the GLUCOCARD® W Blood Glucose Monitoring System in the using of an Alternate Site (palm) as the sampling site in the hands of lay-users, ARKRAY performed studies with 240 lay-user Participants. Participants were provided with labeling for the GLUCOCARD® W Blood Glucose Monitoring System. No other training or prompting was provided to the Participants. When ready, the Participants performed their own testing without assistance. Results were analyzed by comparing blood glucose results from Alternate Site Testing (AST) samples using the GLUCOCARD® W Blood Glucose Monitoring System obtained by the Participants against the reference method value (YSI 2300).

Alternate Site (palm) data on the GLUCOCARD® W Blood Glucose Monitoring System from Participants with Diabetes testing on their palm were evaluated against 2016 FDA Guidance: *Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use* and found to be acceptable. The results are summarized the table below.

Alternate Site (Palm) Data Accuracy

Difference range between the true blood glucose level and the GLUCOCARD® W Blood Glucose Meter result.	**Within ± 5%**	**Within ± 10%**	**Within ± 15%**	**Within ± 20%**
The percent (and number) of meter results that match true blood glucose level within x%	55.8% (134/240)	88.8% (213/240)	97.1% (233/240)	99.2% (238/240)

USER PERFORMANCE

A consumer study was conducted during the course of the clinical trials to evaluate the ease of use/understanding of the GLUCOCARD® W Blood Glucose Monitoring System. The study Participants stated that the GLUCOCARD® W Blood Glucose Monitoring System is ‘easy to use’, has 'instructions for use and messages displayed on the meter' that have 'clarity and usefulness' and that the Participant feels confident that they 'understood how to use the device correctly'.

All Participants in the consumer studies rated the GLUCOCARD® W Blood Glucose Monitoring System User Manual and the overall use of the GLUCOCARD® W Blood Glucose Monitoring System use as at least acceptable. The readability of the labeling using a Flesch-Kincaid analysis was demonstrated to be at or less than an 8th grade level.

ACCURACY AT EXTREME GLUCOSE VALUES

ARKRAY conducted a more robust evaluation between the GLUCOCARD® W Blood Glucose Monitoring System and the YSI 2300 reference analyzer in the extreme upper and lower claimed blood glucose measuring range. Fifty prepared capillary whole blood samples containing glucose concentrations below 80 mg/dL and fifty prepared capillary whole blood samples containing greater than 250 mg/dL glucose concentrations were used in this study.

When evaluated against the comparator YSI results, the values displayed on the GLUCOCARD® W Blood Glucose Meter for samples at the extreme upper and lower claimed blood glucose range generated data with 100% of the data points within 15% of reference analyzer result. These results shown in the table below meets the FDA 2016 Guidance: *Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use* requirements.

Extreme Glucose Values Data Accuracy

Difference range between the true blood glucose level and the GLUCOCARD® W Blood Glucose Meter result.	**Within ± 5%**	**Within ± 10%**	**Within ± 15%**	**Within ± 20%**
The percent (and number) of meter results that match true blood glucose level within x%	52% (52/100)	81% (81/100)	100% (100/100)	100% (100/100)

INTERFERENCE

An evaluation of potential interfering substances on the GLUCOCARD® W Blood Glucose Monitoring System was conducted. Interference was assessed for twenty-seven endogenous and exogenous substances with venous blood samples with three levels of glucose (approximately 60 mg/dL, 120 mg/dL, and 250 mg/dL). The glucose levels were verified by the YSI reference analyzer, using at least four replicates. Each sample was divided into a test pool containing the potential interfering substance and an "untreated" control pool. The relative bias (mg/dL) and percent bias was calculated using the results of the "untreated" control sample relative to the test sample for each concentration of potential interferent.

ARKRAY defined no significant interference when the average percent bias and 95% confidence interval of the test samples relative to the "untreated" control blood sample is within ± 10% at each glucose level. The results are presented in the table below.

Potential Interferents Test Results

Substance	**Highest Concentration Tested with no Observed 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 g/dL

Substance	Highest Concentration Tested with no Observed 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	1015 mg/dL
Tolazamide	40 mg/dL
Tolbutamide	100 mg/dL
Triglycerides	3,000 mg/dL
Uric Acid	24 mg/dL
Xylitol	0.2 mg/dL
Xylose	200 mg/dL

Based on these results, ARKRAY includes the following limitation in the labeling for the GLUCOCARD® W Blood Glucose Monitoring System:

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

HEMATOCRIT

ARKRAY evaluated the effect of hematocrit to assess whether the GLUCOCARD® W Blood Glucose Monitoring System can safely be used across the claimed hematocrit range in the intended use population. Twelve blood samples with varying hematocrit levels were created and the resulting hematocrit range of the twelve-sample panel was from 20% - 70% hematocrit. Hematocrit interference was evaluated on the twelve hematocrit samples, each containing five levels of glucose (approximately 45 mg/dL, 67 mg/dL, 134 mg/dL, 200 mg/dL, and 336 mg/dL). The glucose level for each sample was verified by the YSI reference analyzer with at least four replicates.

A single glucose determination for each sample aliquot was made using three different lots of test strips tested with ten different meters, giving a total of 30 replicates per sample aliquot. All results from the GLUCOCARD® W Blood Glucose Monitoring System supported a claim for a 20% - 70% hematocrit range.

TEST STRIP STABILITY

Stability for the GLUCOCARD® W Blood Glucose Test Strips was evaluated through accelerated and real-time closed bottle and open bottle studies. Closed bottle stability results were reviewed and found to be acceptable to support the claims for an expiry period of 24 months for the GLUCOCARD® W Blood Glucose Test Strips with an expanded Relative Humidity at 1-30°C, 10-90% Relative Humidity. Open bottle stability results were reviewed and found to be acceptable to support an open bottle shelf life of six months for the GLUCOCARD® W Blood Glucose Test Strips.

ENVIRONMENTAL CONDITIONS

Temperature and humidity studies were performed to closely represent actual use conditions experienced by Users of the GLUCOCARD® W Blood Glucose Monitoring System. Operating temperature and humidity conditions were evaluated using ten meters and three test strip lots with venous whole blood samples at three glucose levels (approximately 67 mg/dL, 134 mg/dL, 336 mg/dL). The following temperature and Relative Humidity conditions were tested: 5-8°C / ≤ 10% Relative Humidity, 5-8°C / ≥ 90% Relative Humidity, 40-45°C / ≤ 10% Relative Humidity, 40-45°C / ≥ 90% Relative Humidity.

The test results support that the GLUCOCARD® W Blood Glucose Monitoring System performs in the actual use conditions experienced by Users and the claimed operating temperature from 8°C to 40°C and 10% to 90% Relative Humidity.

ALTITUDE EFFECTS

ARKRAY evaluated the effect of altitude on the performance of the proposed device to assess whether the GLUCOCARD® W Blood Glucose Monitoring System can safely be used up to the altitudes claimed in the labeling. Venous blood samples at six (6) glucose levels (approximately 30-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, 251-400 mg/dL, 450-550 mg/dL) were tested under real-life altitude conditions at sea level and at 10,335 feet (3,150 meters) above sea level. The evaluation included ten meters per test strip lot, three test strip lots, six blood glucose levels, two sample replicates per blood glucose level, for a total of 360 tests. The blood glucose levels were verified by the YSI reference analyzer.

These results support the claims in the labeling that altitudes up to 10,335 feet have no significant effect on the blood glucose measurements from the GLUCOCARD® W Blood Glucose Monitoring System.

ERROR CODES FOR SAMPLES OUTSIDE THE MEASURING RANGE

Analysis was performed to demonstrate that the GLUCOCARD® W Blood Glucose Monitoring System provides the appropriate error codes when measured glucose concentration are outside of the claimed measuring range of 20–600 mg/dL. Venous blood samples with two levels of glucose (≤ 10 mg/dL and 650–700 mg/dL) were created. The glucose levels were verified by the YSI reference analyzer. Three different lots of test strips were tested using ten different meters.

When tested, the blood glucose ≤ 10 mg/dL samples caused a "Lo" Error Code and the blood glucose 650 mg/dL samples caused a "Hi" Error Code to be displayed on the meters. Testing demonstrated that the GLUCOCARD® W Blood Glucose Monitoring System will supply the User with the appropriate error codes when measuring blood glucose concentrations that are outside of the claimed measuring range of 20–600 mg/dL. The results of this study further support that the GLUCOCARD® W Blood Glucose Monitoring System claimed measuring range of 20–600 mg/dL. The meter will display the "Lo" Error Code when the result is less than 20 mg/dL and the "Hi" Error Code when the result is greater than 600 mg/dL.

SHORT SAMPLE DETECTION

To avoid the risk of inaccurate results, GLUCOCARD® W Blood Glucose Monitoring System can detect that a short blood sample has been applied to the test strip and will not provide a result to the User. Short sample detection was assessed. Short sample testing demonstrated that the GLUCOCARD® W Blood Glucose Monitoring System requires a minimum sample volume of 0.5 µL to provide accurate glucose measurements to the User. Volumes less than 0.5 µL do not provide a glucose result to the User.

OTHER SUPPORTIVE PERFORMANCE CHARACTERISTICS STUDIES

The following tests were performed to demonstrate support for GLUCOCARD® W Blood Glucose Monitoring System claims: sample perturbation testing, intermittent sampling testing, and testing with used test strips.

8. Substantial Equivalence Conclusion

The GLUCOCARD® W Blood Glucose Monitoring System is substantially equivalent to the predicate GLUCOCARD® Vital™ Blood Glucose Monitoring System based on comparisons of the device classifications, intended use, and technological characteristics. Non-clinical and clinical performance testing successfully confirmed the suitability of the GLUCOCARD® W Blood Glucose Monitoring System for the intended uses and demonstrated the device is as safe, as effective, and perform as well as the predicate device as required per 21 CFR § 807.92(b)(3).