1. Administrative Information

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2. Device Information

Trade Name	GLUCOCARD® W onyx 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

3. Predicate Device Information

Predicate Device Name	Predicate Device 510(k) Number
GLUCOCARD® W Blood Glucose Monitoring System Including GLUCOCARD® W Blood Glucose Test Strips and Assure® Control–Control Solutions	K170064

4. Device Description

The GLUCOCARD® W onyx Blood Glucose Monitoring System is designed to quantitatively determine glucose concentrations in fresh capillary whole blood samples. The

GLUCOCARD® W onyx Blood Glucose Monitoring System consists of a battery-powered GLUCOCARD® W onyx Blood Glucose Meter, disposable GLUCOCARD® W Blood Glucose Test Strips and Assure® Control–Control Solution (Levels 1, 2, and 3). The GLUCOCARD® W onyx 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 onyx 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 the glucose level in the blood.

4.1 Device Features

The GLUCOCARD® W onyx Blood Glucose Monitoring System has the following device features.

- **Data Transmission**: Device has the capability to communicate with an external PC using a commercially available USB cable or the added capability to communicate with mobile devices via Bluetooth wireless technology.

- **Enhanced Robustness and Ease of Use**: Features such as the below are incorporated to enhance robustness and also for ease of use

  a) Auto coding function: Reads information recorded in the sensor and automatically corrects sensor sensitivity per manufacturing lot.

  b) Temperature correction function: Reads ambient temperature and corrects impact of temperature on measurement results.

  c) Hematocrit correction function: Obtains hematocrit value from calibration curve for peak top and hematocrit values to correct hematocrit impact on measurement results.

  d) Sample auto detection function: Automatically detects if a sample is whole blood or control solution.

  e) Sensor insertion/detection function: Detects sensor insertion automatically and turns the power on.

  f) Sensor removal detection function: Automatically detects sensor removal and turns the power off.

g) Flag setting function: Users can manually set flags to measurement results to help categorize and identify results.

h) Daylight Savings Time feature. Users can set the meter clock to automatically change the time to Daylight Savings Time as desired.

5. Indications for Use

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

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

Table 1: Side-by-Side Comparison, Predicate Device vs. Proposed Device

COMPONENT/ CHARACTERISTIC	PREDICATE	PROPOSED	COMPARISON
Blood Glucose Monitoring System			
510(k) Number	K170064	K183306	N/A

COMPONENT/ CHARACTERISTIC	PREDICATE	PROPOSED	COMPARISON
Monitoring System	GLUCOCARD® W Blood Glucose Monitoring System	GLUCOCARD® W onyx Blood Glucose Monitoring System	N/A Same except
Intended Use and Indications 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 onyx Blood Glucose Monitoring System is comprised of GLUCOCARD® W onyx Blood Glucose Meter and GLUCOCARD® W Blood Glucose Test Strips. The GLUCOCARD® W onyx 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 onyx Blood Glucose Monitoring System is intended to be used by a single person and should not	Blood Glucose Meter and System trade names were updated

COMPONENT/ CHARACTERISTIC	PREDICATE	PROPOSED	COMPARISON
	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).	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).	
Measurement Method	Amperometric	Amperometric	Same
Result Range	20 to 600 mg/dL	20 to 600 mg/dL	Same
Sample Type	Fresh Capillary Whole Blood*	Fresh Capillary Whole Blood*	Same
Calibration Reference	Plasma referenced	Plasma referenced	Same
Sample Application	Apply blood to end, capillary fill	Apply blood to end, capillary fill	Same
Blood Source	Fingertip, palm	Fingertip, palm	Same
Calibration Curve	Automatic coded calibration	Automatic coded calibration	Same
Operating Temperature Range	46°F to 104°F 8°C to 40°C	46°F to 104°F 8°C to 40°C	Same
Temperature Compensation	Automatic compensation using built-in thermosensor	Automatic compensation using built-in thermosensor	Same
Operating Humidity Range	10% to 90% Relative Humidity (No condensation)	10% to 90% Relative Humidity (No condensation)	Same
Maximum Altitude	10,335 ft. (3,150 m)	10,335 ft. (3,150 m)	Same

COMPONENT/ CHARACTERISTIC	PREDICATE	PROPOSED	COMPARISON
Hematocrit Range	20-70%	20-70%	Same
Hematocrit Correction Function	Yes	Yes	Same
Communication Function	Micro USB Port	Micro USB Port Wireless communication function using Bluetooth 4.0	Same for USB Port communication Addition of wireless communication function to enable sending results to mobile devices
Memory Capacity	500 Test Results	500 Test Results	Same
Minimum Sample Volume	0.5 µL	0.5 µL	Same
Test Time	7 Seconds	7 Seconds	Same
Power On	Insert Test Strip into Meter	Insert Test Strip into Meter	Same
Auto Power Off	Two Minutes after Last User Operation (Five Minutes when Waiting for Blood Application)	Two Minutes after Last User Operation (Five Minutes when Waiting for Blood Application)	Same
Sample Auto Detection Function	Automatically Detects if a Sample is Whole Blood or Control Solution	Automatically Detects if a Sample is Whole Blood or Control Solution	Same
Average Calculations	7, 14, 30, 60, 90 days	7, 14, 30, 60, 90 days	Same
Pre-set flag for Low or High Blood Sugar	Yes – Hi and Lo flags set at >600 mg/dL and < 20mg/dL, respectively	Yes – Hi and Lo flags set at >600 mg/dL and < 20mg/dL, respectively	Same
User set indicator for hypoglycemia	Yes	Yes	Same

COMPONENT/ CHARACTERISTIC	PREDICATE	PROPOSED	COMPARISON
User set indicator for hyperglycemia	No	Yes	Addition of a user-set hyperglycemia indicator for results over a determined value (with input from user's healthcare provider)
User set flags for results	Before-Meals After-Meals	Before-Meals After-Meals Before Go to Bed	Same for mealtime results flags Addition of a user-set Before Go To Bed Flag for results taken before bedtime
Validated Cleaning and Disinfection Instructions	Yes	Yes	Same
Buttons and Function	Three Button- Front of Meter	Three Button - Left Side of Meter	Same number of buttons Change in location, orientation and material due to redesign of meter resulting from battery change due to Bluetooth module addition

COMPONENT/ CHARACTERISTIC	PREDICATE	PROPOSED	COMPARISON
Dimensions	84 mm x 50 mm x 17.6 mm	94 mm x 57 mm x 18.5 mm	Larger dimension due to change in components (battery) resulting from Bluetooth module addition
Weight	47 g	70 g	Heavier due to change in components (battery) needed for Bluetooth module addition
Batteries	1 x 3-volt lithium battery (CR2032)	3-volt LR03/2 x 1.5-volt AAA	Change in battery type needed for Bluetooth module addition
Display	Segment display	Negative segment display	Change to white lettering on black background for ease of reading
Display Backlight	No	Yes	Addition of backlight to display to aid in reading
Sensor Port Light	No	Yes	Addition of light to sensor port to aid in inserting test strip
Test Strips	GLUCOCARD® W Blood Glucose Test Strips	GLUCOCARD® W Blood Glucose Test Strips	Same
Control Solution	Assure® Control–Control Solution	Assure® Control–Control Solution	Same

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

7. Previous FDA Submissions and Communications Regarding This Device

There have not been any previous FDA communications nor submissions regarding the proposed device.

8. Substantial Equivalence Conclusion

The GLUCOCARD® W onyx Blood Glucose Monitoring System has the following similarities to the GLUCOCARD W Blood Glucose Monitoring System.

Both the predicate GLUCOCARD® W and GLUCOCARD® W onyx Blood Glucose Monitoring Systems:

- Have the same intended use and indications for use
- Use the same operating technology
- Use the same test strips and control solution
- Have the same performance, measurement range, use environment and calibration functions
- Have the same shelf life

In summary, the GLUCOCARD® W onyx Blood Glucose Monitoring System is substantially equivalent to the predicate GLUCOCARD® W Blood Glucose Monitoring System based on the above comparisons.