

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

A. 510(k) Number:

k082521

B. Purpose for Submission:

Clearance of a new device

C. Measurand:

Whole blood Glucose and Blood Pressure

D. Type of Test:

Blood Glucose Concentration through a Quantitative Amperometric Assay (Glucose Oxidase)

Blood Pressure – Non-invasive Oscillometric

E. Applicant:

Card Guard Scientific Survival, Ltd.

F. Proprietary and Established Names:

PMP⁴ Easy2Check Personal Wireless Blood Pressure and Blood Glucose Monitor

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1345, Glucose Test System

21 CFR §870.1130, Noninvasive blood pressure measurement system

2. Classification:

Class II (Glucose Test System)

Class II (Blood Pressure Measurement System)

3. Product code:

NBW, CGA, DXN

4. Panel:

75, Clinical Chemistry – Glucose Test System

74, Cardiovascular – Blood Pressure Measurement System

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Easy2Check blood glucose and blood pressure monitoring system is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the following alternative sites: the palm, the forearm, the upper-arm, the calf

and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus. The alternative site testing in the systems can be used only during steady-state blood glucose conditions.

The system is also intended to be used to measure non-invasively the systolic and diastolic blood pressure and pulse rate of an adult individual, over age 16, at home. The blood pressure is measured by using a technique in which an inflatable cuff is wrapped around the arm. The cuff circumference is limited to 9.4”~13.8”.

This system offers wireless communication function which is able to transmit the test result to other devices, such as PC.

3. Special conditions for use statement(s):

The alternative site testing in the Easy2Check Blood Glucose and Blood Pressure Monitoring System can be used only during steady-state blood glucose conditions.

Not for diagnosis or screening for diabetes mellitus

Not for use on neonates

Not for use on patients who are dehydrated, in shock, critically ill, or in a hyperosmolar state.

4. Special instrument requirements:

Easy2Check Blood Glucose and Blood Pressure Monitoring System

I. Device Description:

The PMP⁴ Easy2Check Personal Wireless Blood Pressure and Blood Glucose Monitor is identical to TaiDoc’s k080014 submission which is based on the TaiDoc model Clever Chek TD-3250, cleared under k062800, and incorporates wireless data transmission using Bluetooth technology for the data transfer which can transmit the results to a personal computer immediately after the measurement is taken or after the results are retrieved from memory. TaiDoc Technology Corp. has given permission to allow the use of the performance data and software documentation from k080014 (and therefore k062800 and k061073) for use in supporting Card Guard's 510(k) application. The performance data in section M below is the same data found in k062800 and k061073.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Clever Chek TD-3250D Blood Glucose plus Blood Pressure Monitoring System

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

k080014

3. Comparison with predicate:

Similarities		
Item	Devices	Predicate (k061181)
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)

Similarities		
Item	Devices	Predicate (k061181)
Test Range	20 – 600 mg/dL	20 – 600 mg/dL
Hematocrit	20-60%	20-60%
Open Use Time (strip)	90 days	90 days
Wireless Data Transmission	Bluetooth transmission	Bluetooth transmission
Coding	Code strip	Code strip
Type of Reading	Non-invasive, diastolic and systolic blood pressure and pulse rate	Non-invasive, diastolic and systolic blood pressure and pulse rate
Pulse Rate	40-200 beats/min	40-200 beats/min
Stethoscope	Not Required	Not Required
Measuring Range	0-300 mm Hg	0-300 mm Hg
Maximum Cuff Pressure	300 mmHg	300 mmHg
Target Population	Age 16 and above	Age 16 and above

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

ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

L. Test Principle:

For the blood glucose portion: Once a whole blood sample is applied to the sample chamber of the test strip, glucose measurement commences. Glucose measurement is based on electrical potential caused by the reaction of glucose with the reagents contained on the strip's electrodes. The glucose in the sample is oxidized by the enzyme glucose oxidase, producing gluconolactone. The current resulting from this enzymatic reaction is measured and converted to glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample.

For the blood pressure cuff portion: The system adopts the "oscillometric method" as the measuring principle and provides the measurement of the systolic and diastolic blood pressure and heart rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the arm. The pressure sensor converts tiny alterations in arm cuff pressure to electrical signals, analyzing those signals to determine the systolic and diastolic blood pressure and calculating pulse rate.

M. Performance Characteristics (if/when applicable):

The performance data in this section were established in the previously cleared submissions k062800 and k061073.

1. Analytical performance:

a. *Precision/Reproducibility:*

The precision was evaluated on the Easy2Check Blood Glucose and Blood Pressure Monitoring System using replicate measurements of glucose control solutions and spiked anticoagulated venous whole blood. Day to day precision testing was

performed with 3 levels of control solutions each with 3 different lots test strips. Samples were tested with 10 measurements obtained from 10 meters with each level of control solution (for a total of 300 tests) over 10 days. The range for each control solution level is an experienced result in periods of 6 months. Each level was established as an average value first, which for low is 77 mg/dL, for normal is 135 mg/dL, and for high is 325 mg/dL. Then the range of each level was established from the average minus/plus 20% (20% is from ISO15197, minimum acceptable accuracy), giving low ranges of 61 to 93 mg/dL, normal ranges from 108 to 162 mg/dL, and high ranges from 260 to 390 mg/dL. Results are summarized below.

	Low Control Level (61-93 mg/dL)			Mid Control Level (108-162 mg/dL)			High Control Level (260-390 mg/mL)		
Strip Lot	Lot 1 (meters 1-3)	Lot 2 (meters 4-6)	Lot 3 (meters 7-10)	Lot 1 (meters 1-3)	Lot 2 (meters 4-6)	Lot 3 (meters 7-10)	Lot 1 (meters 1-3)	Lot 2 (meters 4-6)	Lot 3 (meters 7-10)
Mean	78.2	78.8	80.1	133.1	137.5	138.4	324.2	326.0	326.2
SD	1.99	1.63	1.78	4.15	4.01	3.95	7.89	8.36	6.65
CV	2.55%	2.07%	2.22%	3.12%	2.92%	2.86%	2.43%	2.57%	2.04%

Within day precision testing was performed with 5 levels of spiked whole blood (with a hematocrit of ~46%) each with 3 different lots test strips. Samples were tested with 10 measurements obtained from 10 meters with each level of control solution (for a total of 500 tests) over 10 days. Results are summarized below.

	Level 1 (30-50 mg/dL)			Level 2 (51-110 mg/dL)			Level 3 (111-150 mg/mL)		
Strip Lot	Lot 1 (meters 1-3)	Lot 2 (meters 4-6)	Lot 3 (meters 7-10)	Lot 1 (meters 1-3)	Lot 2 (meters 4-6)	Lot 3 (meters 7-10)	Lot 1 (meters 1-3)	Lot 2 (meters 4-6)	Lot 3 (meters 7-10)
Mean	41.9	41.7	41.4	91.0	90.8	91.4	143.2	142.8	143.1
SD	2.02	2.04	2.06	2.66	2.79	2.79	3.21	3.88	3.57
CV	4.83%	4.88%	4.98%	2.92%	3.07%	3.07%	2.24%	2.72%	2.50%

	Level 4 (151-250 mg/dL)			Level 5 (251-400 mg/dL)		
Solution Lot	Lot 1 (meters 1-3)	Lot 2 (meters 4-6)	Lot 3 (meters 7-10)	Lot 1 (meters 1-3)	Lot 2 (meters 4-6)	Lot 3 (meters 7-10)
Mean	240.9	236.9	240.6	363.8	364.6	365.3
SD	6.12	5.82	7.15	6.14	7.28	6.20
CV	2.54%	2.46%	2.97%	1.69%	2.00%	1.70%

b. Linearity/assay reportable range:

The linearity of the device was demonstrated by comparing 9 levels of whole blood samples on the system and a glucose reference method (YSI-2300) in k061181. The samples ranged in concentration from a low of approximately 22 mg/dL to a high of approximately 587 mg/dL (from YSI). Linear regression of the comparison data yielded the following relationship: device = (0.9851x YSI-2300) + 5.4, $r^2 = 0.9995$.

The reportable range of the Easy2Check Blood Glucose and Blood Pressure Monitoring System is 20 - 600 mg/dL.

- c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
The controls supplied with this device were previously cleared under k012430 and are being used with this device. Traceability of the meter has been shown to a laboratory analyzer.
- d. *Detection limit:*
20 mg/dL. The sponsor supported this level with a linearity study (above).
- e. *Analytical specificity:*
The specificity of the device was assessed with the Easy2Check Blood Glucose and Blood Pressure Monitoring System. Elevated blood triglycerides and the following substances do not affect results: acetaminophen, dopa, methyldopa, L-dopa and tolbutamide occurring in expected blood concentrations. Reducing substances such as uric acid and ascorbic acid occurring in expected blood concentrations was shown to not cause interference. The altitude study also showed that the percentage of mean difference between strips is within the acceptable range (from ISO15197, minimum acceptance accuracy: within $\pm 20\%$ when glucose concentration $\geq 75\text{mg/dL}$) indicating that the new test strips are equivalent to the predicate strips at the same altitude (up to 10,744 feet). A hematocrit was also performed and the results supported a use of the meter from 20 to 60% hematocrit.
- f. *Assay cut-off:*
Not Applicable.

2. Comparison studies:

- a. *Method comparison with predicate device:*
The Easy2Check Blood Glucose and Blood Pressure Monitoring System for finger stick glucose measurement was demonstrated to be equivalent to a standard method (YSI-2300) and can be used on alternate sites (specifically the capillary blood from finger compared to the palm, forearm, upper arm, calf, and thigh). The accuracy was assessed by having 147 patients from 3 different sites using a standard method compared to finger stick. For the finger stick against the standard method, samples ranged as follows: 10% of samples were 20-50 mg/dL, 36% of samples were 51-110 mg/dL, 29% of samples were 111-150 mg/dL, 11% of samples were 151-250 mg/dL, 15% of samples were 251-600 mg/dL, and 15% of samples were 401-600 mg/dL. For the AST sites, the samples ranged as follows: 40% of samples were 51-110 mg/dL, 30% of samples were 111-150 mg/dL, 20% of samples were 151-250 mg/dL, and 10% of samples were 251-600 mg/dL. All patients blood glucose levels were in a steady state for these studies. The studies are summarized below.

Comparison	N	Slope and y-intercept	r^2
Easy2Check vs. YSI-2300	147	$y = 0.994x + 3.38$	0.984

Difference distribution for glucose concentration <75mg/dL

Difference within ±5mg/dL	Difference within ±10mg/dL	Difference within ±15mg/dL
11/30 (37%)	25/30 (83%)	29/30 (97%)

97% of the individual difference is within ±15mg/dL when glucose concentration is <75mg/dL.

Difference distribution for glucose concentration ≥75mg/dL

Difference within ±5 %	Difference within ±10 %	Difference within ±15 %	Difference within ±20 %
52/117 (44%)	94/117 (83%)	110/117 (94%)	113/117 (97%)

97% of the individual difference is within ±20% when glucose concentration is ≥75mg/dL.

	YSI vs. Finger	Finger vs. Palm	Finger vs. Forearm	Finger vs. Upper arm	Finger vs. Calf	Finger vs. Thigh
N	147	121	119	115	117	113
Slope	0.994	0.991	0.948	0.945	1.01	0.931
Intercept	3.38	-0.091	5.92	3.21	-2.63	4.89
r ²	0.984	0.971	0.951	0.951	0.951	0.945

Finger versus YSI and each site met the ISO 15197 requirement of ninety-five percent (95 %) of the individual glucose results falling within ±15 mg/dL of the results of the manufacturer’s measurement procedure at glucose concentrations for samples <75 mg/dL and within ± 20 % at glucose concentrations ≥75 mg/dL. These results are summarized in the table below.

Site	Finger	Palm	Forearm	Upper arm	Calf	Thigh
N	147	121	119	115	117	113
Percentage That Met ISO Requirement	97% (142/147)	97% (117/121)	95% (113/119)	96% (110/115)	96% (112/117)	96% (108/113)

The sponsor also has instructions in the labeling for each meter that indicate at what intervals alternate site testing (AST) can be used and when AST should not be used.

The blood pressure monitoring component of the Easy2Check Blood Glucose and Blood Pressure Monitoring System was compared against a mercury sphygmomanometer and a total of 270 measurements. The results generated demonstrated a mean difference of: systole = 1.78 mmHg, SD = 5.65 mmHg, diastole = 1.2 mmHg, SD = 5.21. This meets the ± 5 mmHg and ± 8 mmHg SD allowable under the ANSI/AAMI SP10. The patient contacting material in this device is medical grade coated polyester fabric.

b. Matrix comparison:

Not applicable. Capillary whole blood is the only indicated matrix.

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):

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

The sponsor included the following Expected Values for normal glucose levels in their strip labeling:

Fasting and before meal¹ 70-110 mg/dL

2 hours after meals² Less than 140 mg/dL

¹: Sacks, DB in “Carbohydrates”, Burtis, CA, Ashwood, ER (ed), Tietz Textbook of Clinical Chemistry, Philadelphia, WB Saunders Company, 1999.

²: ADA Clinical Practice Recommendations 2003

N. Instrument Name:

PMP⁴ Easy2Check Personal Wireless Blood Pressure and Blood Glucose Monitor

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional readings.

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, the palm, the forearm, the upper-arm, the calf, and the thigh only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

A code strip is provided with each batch of test strips to calibrate the meter for that batch. No further calibrations are required of the user.

6. Quality Control:

The sponsor is providing a high and low glucose control solution with this device. When a test strip is inserted into the meter, the control mode can be activated. This prevents control results from being stored in the internal memory. An acceptable range for each control level is printed on the test strip vial label. The user is referred to the troubleshooting section of the owner's manual if control results fall outside these ranges.

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

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.