

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

A. 510(k) Number:

k061528

B. Purpose for Submission:

Re-branding and Re-labeling of the Taidoc Check Blood Glucose Test System (k041107)

C. Measurand:

Glucose

D. Type of Test:

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

E. Applicant:

Card Guard Scientific Survival Ltd.

F. Proprietary and Established Names:

SelfCheck Gluco

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1345, Glucose test system

21 CFR § 862.1660, Quality control material (assayed and unassayed)

2. Classification:

Class II

Class I, reserved

3. Product code:

NBW, CGA, JJX

4. Panel:

75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

The Card Guard SelfCheck Gluco glucose test system is intended for use in the quantitative measurement of glucose in whole blood taken from the finger. 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, and is not intended for use on neonates.

3. Special conditions for use statement(s):

For over the counter and professional use.

Not intended for use on neonates.

4. Special instrument requirements:
Card Guard SelfCheck Gluco glucose test system

I. Device Description:

The Card Guard SelfCheck Gluco glucose test system consists of a glucose test meter, test strips, two levels of control solution, and a commercially available (510(k) cleared) lancing device. It is identical to TaiDoc's Check Blood Glucose Test System, k041107.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Bayer Glucometer Elite Diabetes Care System
2. Predicate 510(k) number(s):
k020208
3. Comparison with predicate:
Comparison with a predicate was outlined in k041107.

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

The following references were stated in k041107:

CLSI Guideline EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices

CLSI Guideline EP6-P2: Evaluation of the Linearity of Quantitative Analytical Methods

CLSI Guideline EP7-A: Interference Testing in Clinical Chemistry

CLSI Guideline EP9-A: Method Comparison and Bias Estimation Using Patient Samples
prEN 13640

ISO 15197

IEC 60601-1 (1998), IEC 61010-1 (1990), EN 60601-1 (2001), EN 61010-1 (2001)

L. Test Principle:

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.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Precision and reproducibility were demonstrated in k041107.
 - b. *Linearity/assay reportable range:*
Linearity and the reportable range were demonstrated in k041107.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Two levels of control material (normal and high) are provided for use with the test system. The target values are 125 mg/dL and 300 mg/dL and are prepared gravimetrically in an aqueous matrix. The open, closed, and transport stability testing protocols were described in k041107.

d. *Detection limit:*
The detection limit of 20 mg/dL was demonstrated in k041107.

e. *Analytical specificity:*
In k041107, the sponsor established that hematocrit (20-60%), temperature, humidity, drop (impact) effects and vibration, and high altitude (3275 meters) did not affect the meter's performance. No interference (defined as +/- 10% of control) was observed up to the following concentrations in k041107:

Acetaminophen – up to 5 mg/dL

Ascorbic acid – up to 1.25 mg/dL

Dopamine – up to 2 mg/dL

L-Dopa – up to 3 mg/dL

Methyl Dopa – up to >0.5 mg/dL

Tolbutamide – up to 200 mg/dL

Uric acid – up to 10 mg/dL

Triglyceride – up to 2000 mg/dL

The insert states that no interferences are seen at normal physiological levels of these potential interferents as the levels at which interference is observed are above the normal physiological concentrations of these substances.

f. *Assay cut-off:*
Not Applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*
Demonstration that the SelfCheck Gluco is substantially equivalent to a standard clinical chemistry method (YSI-2300) can be found in k041107.

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):*

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:

| Status | Range (mg/dL) | Range (mmol/L) |
|---------------------|---------------|----------------|
| Before meals | 70-110 | 3.9-6.1 |
| 2 hours after meals | <120 | <6.7 |

Source: Krall, L.P. and Beaser, R.S.: Joslin Diabetes Manual. Philadelphia: Lea and Febiger (1989), 138.

N. Instrument Name:

SelfCheck Gluco

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 reviewed applicant's Hazard Analysis and software development processes for this line of product types in k041107. See k041107 for more information.

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. 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:

Two levels of quality control material are provided with the system.

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.