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

A. 510(k) Number:
k041107

B. Purpose for Submission:
Clearance of whole blood glucose test system

C. Analyte:
Whole Blood glucose

D. Type of Test:
Electrochemical biosensor

E. Applicant:
Taidoc Technology Corporation

F. Proprietary and Established Names:
Taidoc Check Blood Glucose Test System

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
3. Product Code:
   NBW, Blood glucose test system, over the counter
   CGA, Glucose test system
   JJX, Single (specified) analyte controls (assayed and unassayed)
4. Panel:
   Clinical Chemistry (75)

H. Intended Use:
1. Intended use(s):

   The Taidoc Check Blood 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.

2. Indication(s) for use:
   See Intended use above
3. Special condition for use statement(s):
   For over the counter and professional use
4. Special instrument Requirements:
   Taidoc Check Glucose meter

I. Device Description:

The Taidoc Check Blood 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Bayer Glucometer Elite Diabetes Care System
2. Predicate K number(s):
   k020208
3. Comparison with predicate:

   The device and the predicate share the same intended use and test principle. Additional similarities and differences are listed below.

Similarities		
Item	**Device**	**Predicate**
Enzyme	Glucose oxidase	Glucose oxidase
Test range	20 – 600 mg/dL	20 – 600 mg/dL
Test strip calibration	Code strip	Code strip
Sample volume	1.8 – 2.5 µL	2 µL
Differences		
Item	**Device**	**Predicate**
Temperature and humidity range	10 – 40 ˚C 5 – 95 % RH	10 – 40 ˚C 20 – 80 % RH
Test time	20 sec	30 sec

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

NCCLS Guideline EP5-A - Evaluation of Precision Performance of Clinical Chemistry Devices

NCCLS Guideline EP6-P2 - Evaluation of the Linearity of Quantitative Analytical Methods

NCCLS Guideline EP7-A - Interference Testing in Clinical Chemistry

NCCLS 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:*

　　　　　　Within day imprecision was evaluated by spiking samples to achieve
　　　　　　5 levels of glucose concentration. The low glucose sample was left
　　　　　　at room temperature until the glucose in the sample was depleted.
　　　　　　Samples were tested 20 times. This testing was performed at 3
　　　　　　different sites. Results are summarized below. (units = mg/dL)

Glucose Conc.		**Site 1**	**Site 2**	**Site 3**
30-50	**Mean**	44.8	45.2	43.9
	SD	1.48	1.14	1.29
	% CV	3.31 %	2.52 %	2.95 %
51-110	**Mean**	99.4	99.4	100.7
	SD	2.06	2.76	2.11
	% CV	2.07 %	2.78 %	2.09 %
111-150	**Mean**	141.3	134.3	142.8
	SD	3.13	5.38	4.06
	% CV	2.21 %	4.01 %	2.84 %
151-250	**Mean**	220.4	227.0	224.5
	SD	12.24	7.65	9.50
	% CV	5.55 %	3.37 %	4.23 %
251-400	**Mean**	305.9	327.8	328.2
	SD	11.14	7.71	8.59
	% CV	3.64 %	2.35 %	2.62 %

Day to day imprecision was evaluated by testing 3 levels of control solutions four times per day for 20 days on each of two meters at each of 3 different test sites. Results are summarized below. (units = mg/dL).

Glucose Conc.		Site 1	Site 2	Site 3
60 – 80	**Mean**	69.7	70.2	69.8
	SD	2.25	2.15	1.90
	% CV	3.22 %	3.06 %	2.73 %
100 – 150	**Mean**	126.8	126.1	126.7
	SD	2.99	5.39	2.59
	% CV	2.36 %	4.28 %	2.04 %
Glucose Conc.		*Site 1*	*Site 2*	*Site 3*
250 - 350	**Mean**	315.6	319.2	323.4
	SD	8.84	10.19	8.89
	% CV	2.80 %	3.19 %	2.75 %

b. *Linearity/assay reportable range:*

Spiked recovery was evaluated by preparing spiked glucose samples across the measuring range and comparing them to a laboratory measurement of the same samples. Whole blood was depleted of glucose by allowing it to sit at room temperature for 24 hours. The blood was then spiked to 11 targeted glucose concentrations (20, 40, 60, 80, 120, 160, 200, 240, 320, 440, and 560 mg/dL). The spiked samples were measured in duplicate and the resultant regression equation when the observed results were plotted against results from a laboratory reference method was $y = 1.0705x + 16.215$ ($R^2 = 0.997$).

The reportable range of the assay is 20 – 600 mg/dL.

c. *Traceability (controls, calibrators, or method):*

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. Expected values are verified for each manufactured lot. The open, closed, and transport stability were tested.

d. *Detection limit:*

20 to 600 mg/dL

e. *Analytical specificity:*

The sponsor tested the effects of hematocrit (20-60%), temperature, humidity, resistance to drop and vibration, and high altitude (3275 meters) on the meter's performance. The sponsor claims that there is no effect of any of these factors on glucose results (defined as within +/- 15 mg/dL difference in samples below 75 mg/dL and within +/- 20% in samples above 75 mg/dL).

The sponsor tested 6 exogenous and 2 endogenous substances for interference with their meter. No interference (defined as +/- 10% of control) was seen to the following concentrations:

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 seen are above the normal observed physiological concentrations of these substances.

f. *Assay cut-off:*
Not applicable

2. Comparison studies:
   a. *Method comparison with predicate device:*

   Clinical technicians obtained blood glucose concentrations from 120 patients at 3 sites using the device and the results were compared to results from venous blood samples from the same patients that were analyzed on a clinical laboratory analyzer. The technician vs. laboratory regression statistics are summarized below for the three sites.

   Site 1: Technician = 1.089(Lab) – 9.8276; r = 0.9869
   Site 2: Technician = 1.0626(Lab) – 6.901; r = 0.9870
   Site 3: Technician = 0.9952(Lab) + 1.8574; r = 0.9866

   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):*

      Clinical technicians obtained blood glucose concentrations from 120 patients at 3 sites using the device and the results were compared to results obtained when the same patients tested their own blood glucose levels. The technician vs. user regression statistics are summarized below for the three sites.

      Site 1: User = 0.8647(Technician) + 15.477; r = 0.9785
      Site 2: User = 0.9812(Technician) + 3.7056; r = 0.9863
      Site 3: User = 0.9937(Technician) + 0.8674; r = 0.9900

      Patients (n = 120) obtained blood glucose concentrations at 3 sites using the device and the results were compared to results from venous blood samples from the same patients that were analyzed on a clinical laboratory analyzer. The user vs. laboratory regression statistics are summarized below for the three sites.

      Site 1: User = 0.9516(Lab) + 5.5478; r = 0.9882
      Site 2: User = 1.0485(Lab) – 3.8361; r = 0.9844
      Site 3: User = 0.9905(Lab) + 2.4982; r = 0.9800

      One hundred users (23 Europeans and 77 Taiwanese) were given the instructions for use and asked to fill out a questionnaire relating to the readability of the Instructions for Use. The insert evaluation showed acceptable readability.

4. Clinical cut-off:
   Not applicable

5. Expected values/Reference range:

   The package insert indicates the following reference range for fasting blood glucose: 70 – 110 mg/dL. The labeling advises that users should consult their physician to determine their own appropriate range.

N. Instrument Name:
Taidoc Check Blood Glucose meter

O. System Descriptions:

1. <u>Modes of Operation</u>:
   Manual – insertion of test strip and sample application start the test
2. <u>Software</u>: software language – Assembly 6502
   Requires RS232 interface, setting buttons, and test strip port

   FDA has reviewed applicant's Hazard Analysis and software development
   processes for this line of product types:
   Yes ___3___ or No _____

3. <u>Sample Identification</u>:
   Not applicable. Sample is fresh capillary blood from a fingerstick. The meter
   stores up to 180 test results.
4. <u>Specimen Sampling and Handling</u>:
   Manual – sample (fresh whole blood) acquired by fingerstick
5. <u>Assay Types</u>:
   Chemistry
6. <u>Reaction Types</u>:
   Electrochemical
7. <u>Calibration</u>:
   Calibration information is contained on a coding strip that is contained in each
   test strip vial. The user codes the meter with the lot code strip and the meter
   stores the calibration information for strips with that code.
8. <u>Quality Control</u>:
   Two levels of quality control material are provided with the system.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "L. Performance Characteristics" Section Of The SE Determination Decision Summary:

Q. Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.