510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:
k082169

B. Purpose for Submission:
New device

C. Measurand:
Whole Blood Glucose

D. Type of Test:
Quantitative (glucose dehydrogenase-FAD)

E. Applicant:
TaiDoc Technology Corporation

F. Proprietary and Established Names:
TaiDoc Pro I Glucose Test Strips

G. Regulatory Information:
1. Regulation section:
   21 CFR 862.1345 Glucose test system
2. Classification:
   Class II
3. Product code:
   NBW, LFR
4. Panel:
   Chemistry (75)

H. Intended Use:
1. Intended use(s):
   See Indications for use below.
2. Indication(s) for use:
   The TaiDoc Pro I Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. The test strips are for use with Clever Chek TD-4222, Clever Chek TD-4230, Clever Chek TD-4231 Blood Glucose Meters and Clever Chek TD-3250C, and Fora Comfort 2 in 1 Blood Glucose plus Blood Pressure Monitors Only.

   It is intended for use by healthcare professionals and the 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.

Professionals may use the test strips to test capillary and venous blood samples, but lay user may not test venous blood samples.

3. <u>Special conditions for use statement(s):</u>
   - For prescription and over-the-counter use
   - Not for neonatal use
   - Not for screening or diagnosis of diabetes
   - Not for patients who are dehydrated, in shock, critically ill, or in a hyperosmolar state.
   - Alternative sites testing is for use at times of steady state only

4. <u>Special instrument requirements:</u>
   For Use with Clever Chek TD-4222, Clever Chek TD-4230, Clever Chek TD-4231 Blood Glucose, Meters and Clever Chek TD-3250C, and Fora Comfort 2 in 1 TD-3260 Blood Glucose plus Blood Pressure Monitors.

I. Device Description:

The TaiDoc Pro I Glucose Test Strip is a firm plastic, dry reagent strip stored in a desiccated vial. Components of the strip: Glucose dehydrogenase (E. coli), electron shuttle, enzyme protector and non-reactive ingredients.

J. Substantial Equivalence Information:

1. <u>Predicate device name(s):</u>
   Roche Diagnostics Accu-CheK Go Test System

2. <u>Predicate K number(s):</u>
   k040796

3. <u>Comparison with predicate:</u>

Similarities		
Item	Proposed Device	Predicate Device
Detection method	Amperometry: measuring a current produced by a chemical reaction	Same
Sample type	Whole blood (capillary and venous)	Same
Operating temperature	50°F- 104°F (10°C-40°C)	Same

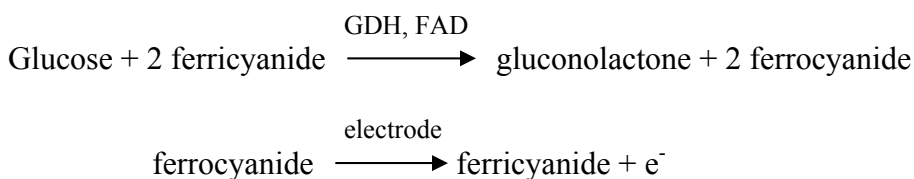| Differences		
Item	Proposed Device	Predicate Device
Enzyme	Glucose dehydrogenase FAD	Glucose dehydrogenase PQQ
Sample volume	0.7 uL	1.5 uL
Measuring range	20 – 600 mg/dL	10 – 600 mg/dL
Reaction time (sec)	7	5
Storage temperature	36°F- 90°F/ 2°C-32°C	36°F- 86°F/ 2°C-30°C
Hematocrit	20-60%	25-65%

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
• ISO 14971: Medical Device Risk Management
• *User Evaluation of Precision Performance of Clinical Chemistry Devices: Approved Guideline* (EP5-A2)
• *Method Comparison and Bias Estimation using Patient Samples: Approved Guideline* (EP9-A2)

L. Test Principle:
A glucose dehydrogenase sensor based on the carbon electrode adopting the amperometric assay is provided. The reaction utilizes the enzyme glucose dehydrogenase to catalyze the formation of gluconolactone from the oxidation of glucose whereby two electrons are produced. Through the mechanism of the mediator, electrical current is generated and it is proportional to the quantity of glucose in the sample.

The reaction principle of reagent depends on following reaction equation:

$$\text{Glucose} + 2 \text{ ferricyanide} \xrightarrow{\text{GDH, FAD}} \text{gluconolactone} + 2 \text{ ferrocyanide}$$

$$\text{ferrocyanide} \xrightarrow{\text{electrode}} \text{ferricyanide} + e^-$$

GDH: glucose dehydrogenase
FAD: flavin adenine dinucleotide

M. Performance Characteristics (if/when applicable):
  1. Analytical performance:
     a. *Precision/Reproducibility:*
        Precision studies were performed using ISO 15197 and CLSI Document EP5-A as guidelines. Three lots of test strips were tested with 10 TaiDoc glucose meters (TD-4230 model).

        Within-day precision (repeatability) was performed by using venous whole

blood which was spiked with dextrose to provide samples at five different glucose concentrations (30 – 50 mg/dL, 51 - 110 mg/dL, 111 – 150 mg/dL, 151 – 250 mg/dL and 251 - 400 mg/dL). Blood samples were tested within 30 minutes and hematocrit was normal (38-54%). 500 measurements were taken for this portion of the study (100 measurements of each sample).

For day-to-day precision (intermediate precision), three control solutions with concentrations of low, normal and high with target levels of 32-52 mg/dL, 69-93 mg/dL, and 196-265 mg/dL were used to ensure no glycolysis effect. Day-to-day precision was performed over 10 days. 300 measurements were taken for this portion of the study (30 measurements per day; 10 measurements per control sample).

Within-day precision:

		Mean	SD	CV (%)
Glucose concentration	30-50 mg/dL	46.1	1.35	2.93
	51-110 mg/dL	103.2	2.80	2.71
	111-150 mg/dL	145.8	2.58	1.77
	151-250 mg/dL	207.6	3.87	1.86
	251-400 mg/dL	330.8	8.34	2.52

Day-to-day precision:

		Mean	SD	CV (%)
Controls	Low	34.4	1.93	5.60
	Normal	79.5	1.80	2.27
	High	218.9	4.27	1.95

b. *Linearity/assay reportable range:*
   The claimed measuring range for this device is 20-600 mg/dL. Nine spiked whole blood samples with different glucose concentration levels in the claimed range were tested:

Level	Glucose concentration (mg/dL)
1	20
2	40
3	60
4	90
5	120
6	200
7	320
8	420
9	600

A YSI-2300 Analyzer was used to verify the glucose concentration of the

samples, and then the samples were measured by two lots of TaiDoc Pro I Glucose Test Strips on a TD-4230 meter.

The samples were prepared and divided into two aliquots. One aliquot was used to perform on the TaiDoc Pro I Glucose Test Strips and the second aliquot was analyzed on the reference method. For each level solution, 10 consecutive tests (with 5 measurements per lot) were performed on each meter.

Linear regression statistics:
range = 22.4 – 587 mg/dL (as measured by the reference method)
y = 0.9983x – 0.164
R^2 = 0.9996

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Calibration: calibration of the test strip is done by entering measurement parameters into the meter before testing, which can be done by users either by inserting the code strip into the meter before testing or by selecting the code number from the meter before testing.

Stability:
Storage Stability Study: The storage claims for this device are: 90 days for open vial of strips stored at 2 – 32 °C and 24 months for unopened vials of strips stored at 2 - 32°C. For the unopened vial stability claim, accelerated testing of the strips was performed. Currently, there is 18 months of real-time stability testing for unopened vials at the appropriate storage temperature. The study protocols, summary of results and acceptance criteria were reviewed and found to be adequate.

d. *Detection limit:*
The sponsor has not conducted studies to determine the limit of detection (LOD), however, as supported by linearity studies, the sponsor has established the measuring range of 20 - 600 mg/dL for the Pro I Glucose Test Strips.

e. *Analytical specificity:*
Hematocrit: The potential effect of hematocrit was evaluated at 20%, 30%, 40%, 50%, and 60% hematocrit levels. Testing was performed with spiked venous whole blood samples from normal, healthy donors. Samples with seven different glucose concentrations spaced across the claimed measuring range (20 – 600 mg/dL) at the different hematocrit levels were measured by using YSI 2300 as a reference method and by using TaiDoc Pro I Glucose Test Strips.
The data supports the sponsor's claim that results generated by their device are comparable to the values of the YSI-2300 instrument at hematocrit levels between 20 – 60%.

Interference Study: Interference testing was conducted to determine the effect of selected endogenous and exogenous substances. Ascorbic acid, acetaminophen, dopamine, uric acid, bilirubin, triglyceride, fructose, galactose and maltose were tested as potential interferents.

Testing was performed in parallel (control versus test samples) and simultaneously to minimize the effects of glucose metabolism. The sponsor used seven blood samples and evaluated two glucose levels. Three to four levels of each compound were evaluated.
Paired differences of glucose measurements between drug-spiked samples and neat control samples were calculated to determine the bias. A criterion of $\pm$ 10% was used as the cutoff for interference. There is no interference observed in all interfering substances at therapeutic or physiological levels either at low or high glucose levels.

Substance	Reference range (mg/dL)	Concentration showing no interference (mg/dL)
Acetaminophen	1-2	5
Ascorbic acid	0.8-1.2	3
Dopamine	0.4-1.6	3.25
Bilirubin	1.2	15
Uric acid	7	10

Interference was seen for the following compounds at concentrations above the therapeutic range for the following: acetaminophen (10 mg/dL), dopamine (6.25 mg/dL), bilirubin (20 mg/dL), and uric acid (15 mg/dL).
No interference was detected when triglyceride, fructose, galactose and maltose were tested.

Temperature/humidity study: A temperature and humidity study was performed to determine the effects of variation in temperature and humidity on the response of Pro I Glucose test strips with control solutions. Testing was conducted using 250 strips and ten glucose meters at three temperatures (10, 25 and 40°C) and two levels of humidity (50 and 60% RH). 60 measurements for each test condition were obtained. Precision and accuracy was calculated for each test condition and found to be acceptable.

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

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

   Comparison to a reference method (YSI-2300):
   Testing was done comparing Pro I Glucose strips (using 5 TaiDoc meters: TD-4222, TD-4230, TD-4231, TD-3250, and TD-3260) against YSI-2300 at

three different sites. 120 subjects, including both men and women of varied ages, were tested by professionals. Samples from 24 to 511 mg/dL were included. Each fresh capillary whole blood sample used was from a different individual, except for samples with concentrations less than 40 mg/dL and greater than 400 mg/dL. For those specimens, a pooled capillary whole blood specimen spiked to the desired level was used. Three lots of strips were tested. The correlation data (regression analysis) is summarized as below:

Total N=120	TD-4222 vs. YSI-2300	TD-4230 vs. YSI-2300	TD-4231 vs. YSI-2300	TD-3250 vs. YSI-2300	TD-3260 vs. YSI-2300
Slope	0.981	1.004	1.012	0.979	0.971
y-intercept	-0.288	-1.905	-0.957	0.510	-0.273
R^2	0.990	0.993	0.992	0.989	0.991

100% of the samples tested with the proposed device had measurements fall within ± 15 mg/dL of the measurements obtained with the YSI-2300 for glucose concentrations less than 75 mg/dL.

98% of the samples tested with the proposed device had measurements fall within ± 20% of measurements made with the YSI-2300 for glucose concentrations equal to or greater than 75 mg/dL.

Comparison to a predicate device:
A 510(k) cleared device, k040796, was used as the comparative method. This device comes from the same manufacturer. YSI-2300 analyzer is used as the reference method to check the accuracy of both test method and comparative method. The evaluation was done at 3 sites with 120 samples over 3 weeks with three different lots of strips and 5 different models of TaiDoc meters. Samples ranged from 24 – 511 mg/dL. Fresh capillary whole blood from finger stick was used for samples 40 – 400 mg/dL. For those specimens less than 40 mg/dL and greater than 400 mg/dL, a pooled capillary whole blood specimen was used and spiked to the desired level.

Total N=120	TD-4222 vs. Accu-Chek Go	TD-4230 vs. Accu-Chek Go	TD-4231 vs. Accu-check Go
Slope	0.924	0.948	0.958
y intercept	2.052	0.305	0.851
r^2	0.975	0.981	0.986

Total N=120	TD-3250 vs. Accu-Chek Go	TD-3260 vs. Accu-Chek Go
Slope	0.924	0.915
y intercept	2.639	2.003
r^2	0.978	0.977

b. *Matrix comparison:*

Venous blood samples: Testing was done comparing venous blood samples evaluated with the Pro I Glucose strip (using 5 TaiDoc meters: TD-4222, TD-4230, TD-4231, TD-3250C, and TD-3260) against YSI-2300 at three different sites. 100 subjects were tested by professionals. Samples from 28 to 510 mg/dL were included. Each fresh capillary whole blood sample used was from a different individual except for samples with blood glucose concentrations less than 40 mg/dL and greater than 400 mg/dL. For those specimens, a pooled capillary whole blood specimen was used and spiked to the desired level. Three lots of strips were tested. The correlation data (regression analysis) is summarized as below:

Total N=100	TD-4222 vs. YSI-2300	TD-4230 vs. YSI-2300	TD-4231 vs. YSI-2300	TD-3250 vs. YSI-2300	TD-3260 vs. YSI-2300
Slope	0.986	0.989	0.976	0.979	0.975
y-intercept	1.007	1.019	1.010	1.002	0.982
R^2	-0.102	1.443	0.473	1.111	0.375

Glucose meter	% of the individual difference is within ± 15 mg/dL when the glucose conc. is < 75 mg/dL
TD-4222	100% (20/20)
TD-4230	100% (20/20)
TD-4231	100% (20/20)
TD-3250C	100% (20/20)
TD-3260	100% (20/20)

Glucose meter	% of the individual difference is within ±20% when the glucose conc. is ≥ 75 mg/dL
TD-4222	98% (78/80)
TD-4230	100% (80/80)
TD-4231	98% (78/80)
TD-3250C	99% (79/80)
TD-3260	99% (79/80)

Alternative site testing: see 3.c. (Other clinical supportive data) below.

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):

Consumer Study & Alternative site testing: Participants were instructed to read the user manual and perform testing on the finger using the Pro I test strips with the TD-4222, TD-4230, TD-4231, TD-3250, and TD-3260 blood glucose monitoring systems. Next, professionals obtained fingertip blood samples from the participants and performed the glucose testing with these strips and meters. Lastly, the lay user tested at all five alternative sites immediately followed by testing with finger stick blood. 110 participants were tested at three sites.

Results for professional vs. lay-user:

98% (108/110) of the individual differences were within ± 15 mg/dL when the glucose concentration is < 75 mg/dL and within ±20% when the glucose concentration is ≥ 75 mg/dL.

	Site 1 (n = 37)	Site 2 (n = 38)	Site 3 (n = 35)
Slope	1.025	1.030	1.024
y intercept	-1.173	-3.962	-2.998
r^2	0,979	0.986	0.977

The sponsor provided a readability study that indicated that the test strip package insert labeling is at an 8th grade reading level or below.

Results for Alternative Site Testing:

Difference distribution for glucose concentration < 75 mg/dL for Pro I Glucose Test Strips:

Difference	Palm		Forearm		Upper arm		Calf		Thigh	
within ±5mg/dL	46%	6/13	31%	4/13	54%	7/13	62%	8/13	69%	9/13
within ±10mg/dL	92%	12/13	85%	11/13	92%	12/13	85%	11/13	85%	11/13
within ±15mg/dL	100%	13/13	100%	13/13	100%	13/13	100%	13/13	100%	13/13

Difference distribution for glucose concentration ≥ 75 mg/dL for Pro I Glucose Test Strips:

Difference	Palm		Forearm		Upper arm		Calf		Thigh	
within ±5mg/dL	52%	45/87	41%	36/87	59%	51/87	45%	39/87	51%	44/87
within ±10mg/dL	85%	74/87	86%	75/87	87%	76/87	87%	76/87	79%	69/87
within ±15mg/dL	97%	84/87	97%	84/87	97%	84/87	98%	85/87	90%	78/87
within ±20mg/dL	98%	85/87	98%	85/87	99%	86/87	99%	86/87	97%	84/87

Regression analysis:

N=100	Palm vs. finger	Forearm vs. finger	Upper arm vs. finger	Calf vs. finger	Thigh vs. finger
Slope	0.980	0.991	1.004	.0999	0.986
y intercept	1.484	-0.949	-2.050	-0.790	-1.412
R^2	0.982	0.985	0.988	0.982	0.981

The sponsor also has labeling indicating the conditions under which AST can be used and when AST should not be used.

4. Clinical cut-off:
   Not applicable.

5. Expected values/Reference range:
   The sponsor included the following expected non-diabetic values for normal glucose levels in their labeling:

   Fasting and before meals - 70-110 mg/dL (3.9-6.1 mmol/L)[1]
   Hours after meals - Less than 140 mg/dL (7.8mmol/L)[2]

   [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. **Proposed Labeling:**
   The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

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