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

A. 510(k) Number:
k100322

B. Purpose for Submission:
Clearance of a 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:
TD-4277 Blood Glucose Monitoring System, Model 4277

G. Regulatory Information:

1. Regulation section:
   21CFR 862.1345-Glucose test system
   21CFR 862.1660 Quality control material (assayed and unassayed)
2. Classification:
   II, and I, reserved
3. Product code:
   NBW System, Test, Blood Glucose, Over the Counter
   LFR Glucose Dehydrogenase, Glucose
   JJX Single (Specified) Analyte Controls (Assayed and Unassayed)
4. Panel:
   75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):
   See indications(s) for use below
2. Indication(s) for use:
   TD-4277 Blood Glucose Monitoring System, Model TD-4277 is intended for use in the quantitative measurement of glucose in fresh capillary whole blood 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.

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

3. Special conditions for use statement(s):
   - Not intended for diagnosis or screening of diabetes mellitus
   - Not intended for use on neonates
   - For in vitro diagnostic use only
   - Not for use on critically ill patients, patients in shock, dehydrated patients, hypotensive patients or hyperosmolar patients

4. Special instrument requirements:
   TD-4277 Blood Glucose Monitoring System

I. Device Description:

TD-4277 Blood Glucose Monitoring System consists of a blood glucose meter, blood glucose test strips, control solutions, the lancing device, and lancets.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   TaiDoc Pro I Glucose Test Strip
   FORA G30 blood glucose monitoring system

2. Predicate 510(k) number(s):
   k082169, k090187 respectively

3. Comparison with predicate:

Item	Predicate device	Predicate device	Proposed device
Product name	TaiDoc Professional I Glucose Test Strips	FORA G30 blood glucose monitoring system	TD-4277 blood glucose monitoring system
Model no	TD-4351 (K082169)	TD-4241 (K090187)	TD-4277
Indication for use	For use in the quantitative measurement of glucose in fresh capillary whole blood. 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.	Same	Same
Alternative Site Testing	Yes	Yes	No
Detection method	Amperometry: measuring a current produced by a chemical reaction	Same	Same
Enzyme	Glucose dehydrogenase (FAD)	Glucose oxidase	Glucose dehydrogenase - FAD
Power source	n/a	1 x CR2032 battery (3V)	2 x 1.5V AAA batteries
Temperature compensation	n/a	Automatic compensation with built-in thermistor	Same as FORA G30 predicate
Reaction time (sec)	7	5	5
Measurement range	10-600 mg/dL	20-600 mg/dL	20-600 mg/dL
Test Strip Calibration	n/a	One code function (No Code)	One code function (No Code)

Item	Predicate device	Predicate device	Proposed device
Product name	TaiDoc Professional I Glucose Test Strips	FORA G30 blood glucose monitoring system	TD-4277 blood glucose monitoring system
Model no	TD-4351 (K082169)	TD-4241 (K090187)	TD-4277
Measurement mode	n/a	General, AC, PC and quality control	Same as FORA G30 predicate
Special message	n/a	Lo/Hi/Ketone	Same as FORA G30 predicate
Memory feature	n/a	450 measurements	1000 measurements
Power saving	n/a	Auto turn-off after 3 minutes without action	Same as FORA G30 predicate
Transmission Function	n/a	Uses RS232 cable to transmit data to computer	Uses USB cable to transmit data to computer
Product name	TaiDoc Pro I Glucose Test Strips	FORA G30 blood glucose test strips	TD-4277 blood glucose test strips
Reaction time	7 Sec	5 sec	5 sec
Sample volume	0.7μL	0.5μL	0.5μL
Sample type	Whole blood (capillary and venous)	Whole blood (capillary)	Whole blood (capillary and venous)

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 Devices – Application Of Risk Management To Medical Devices
- CLSI - Interference Testing in Clinical Chemistry - EP07-A2

L. Test Principle:

Glucose dehydrogenase assay and amperometric technology is used. 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.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
      Precision includes intermediate precision (day-to-day precision) and repeatability (within-day precision) on three meters. For intermediate

precision, three level glucose control solutions were used instead of blood specimen to prevent glucose degradation effect (glycolysis), and this evaluation was performed for ten days. Repeatability was performed at 5 levels with spiked venous blood samples as short a period of time (30 minutes) as possible to minimize the effect of glycolysis.

Intermediate Precision

Control levels	Low (30-50 mg/dL)			Normal (96-144 mg/dL)			High(280-420 mg/dL)		
meter	1	2	3	1	2	3	1	2	3
Mean	44.2	43.1	43.8	132.0	133.0	132.1	338.0	338.7	336.9
SD	2.17	1.89	2.18	4.87	4.88	4.04	11.04	10.87	13.14
CV	4.91%	4.38%	4.98%	3.69%	3.67%	3.06%	3.27%	3.21%	3.90%
Overall									
Mean		43.7			132.3			337.8	
SD		2.12			4.53			11.78	
CV		4.84%			3.43%			3.49%	

Repeatability

Interval levels	1 (30-50 mg/dL)			2 (51-110 mg/dL)			3 (111-150 mg/dL)		
meter	1	2	3	1	2	3	1	2	3
Mean	44.0	42.8	43.6	84.7	84.4	86.0	136.2	133.7	137.3
SD	2.05	2.06	2.06	2.82	3.24	2.75	4.99	4.37	5.06
CV	4.66%	4.38%	4.98%	3.69%	3.67%	3.06%	3.27%	3.21%	3.90%
Overall									
Mean		43.5			85.2			135.9	
SD		2.10			2.98			5.03	
CV		4.82%			3.50%			3.70%	

Repeatability (cont.)

Interval levels	4 (151-250mg/dL)			5 (251-400 mg/dL)		
meter	1	2	3	1	2	3
Mean	222.8	219.4	220.5	381.9	385.7	381.7
SD	7.12	6.76	6.12	9.91	8.78	8.59
CV	3.20%	3.08%	2.78%	2.60%	2.28%	2.25%
Overall						
Mean		220.8			383.0	
SD		6.70			9.15	
CV		3.03%			2.39%	

b. *Linearity/assay reportable range:*
Testing was conducted using venous blood spiked with D-glucose to provide 11 samples spaced across the range of <20 mg/dL to >700 mg/dL. Testing was conducted using TD-4277 meter with TD-4277 test strips, and YSI-2300 glucose analyzer as the reference method.

Samples were divided into two aliquots. One aliquot was used to perform on the TD-4277 meter and the second aliquot was analyzed on the YSI. For each level solution, 5 consecutive tests were performed by TD-4277 and YSI each.

Regression analysis calculated in the range 16.8-669 mg/dL is:

$Y = 1.0268x - 6.8852$

R^2 0.9977

The applicant is using this study to support the claimed measuring range of 20-600 mg/dL

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Control solutions are prepared to fall within each of three levels 35 – 65, 112-168 and 224 -336 and then check against YSI-2300. Acceptance Criteria is if the coefficient of variation (CV%) of each level of control solution is less than 5% in both measurement results by glucose meter, and YSI-2300, and the mean values of the measurement results by a glucose meter is within the specified range of values.

Control open/closed stability claimed is based on real time studies, based on the coefficient of variation (C.V %) for each level of the control solution is less than 5% in measurement results by YSI-2300 and the mean values of the measurement results by a glucose meter is within the specified range of values.

The results demonstrated that the Control Solution (Level 1, 2, 3) are stable for 90 days after opening, and have a shelf-life of 24 months by meeting the acceptance criteria when stored at 36°F to 86°F (2 - 32°C).

The strip storage claims 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.

d. *Detection limit:*

The measuring range of the system is 20 - 600 mg/dL. This range was verified by the linearity study in section M.1.b above.

e. *Analytical specificity:*

Seven volunteer subjects were healthy and had not taken medications prior to blood donation. Blood was obtained from the forearm of fasting volunteers and collected in 5-mL lithium EDTA Vacutainers. The high glucose level (300mg/dL) was achieved by adding 10% dextrose solution to the blood pool.

The below table is from an evaluation of the dose-response relationship where 5 endogenous and exogenous concentrations from therapeutic (physiological) to toxic were performed 4 times each at low (75-85 mg/dL) and high (300 mg/dL) glucose levels. A criterion of ± 10% was used as the cutoff for interference.

Exogenous substance

	Therapeutic levels (mg/dL)	*Exogenous* Test concentration (mg/dL)	Low glucose level (75-85 mg/dL)	High glucose level (300 mg/dL)
Acetaminophen	1-2	20	10 mg/dL	10 mg/dL
Ascorbic acid	0.8-1.2	3	No interference up to test concentration	No interference up to test concentration
Dopamine	0.4-1.6	13	6.25 mg/dL	3.25 mg/dL
L-dopa	0.02 - 0.28	2.8	0.7	1.4
Methyl-dopa	0.1 - 0.5	2.5	1.25	No interference up to test concentration

Endogenous substance

	Physiological levels (mg/dL)	*Endogenous* Test Concentration (mg/dL)	Low glucose level (75-85 mg/dL)	High glucose level (300 mg/dL)
Uric acid	7	20	15 mg/dL	20 mg/dL
Triglyceride	190	2000	No interference up to test concentration	No interference up to test concentration
Bilirubin	1.2	20	20 mg/dL	20 mg/dL
Fructose	100	1000	No interference up to test concentration	No interference up to test concentration
Galactose	100	1000	No interference up to test concentration	No interference up to test concentration
Maltose	100	1000	No interference up to test concentration	No interference up to test concentration
Xylose	50	50	50 mg/dL	50 mg/dL

The above table lists the drug concentrations at which interference with glucose measurements was greater than ±10%. Most of the concentrations are higher than therapeutic or physiological levels.

There were no significant interferences observed for galactose, maltose and fructose, however, xylose showed a significant interference for concentrations above 50mg/dL in both high and low glucose levels.

No interference was observed in the rest of the interfering substances at therapeutic or physiological levels either at low or high glucose levels.

f. Assay cut-off:
Not Applicable

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

200 Samples from 35 to 467 mg/dL were included. The fresh capillary whole blood samples were from different individuals except those with blood glucose concentration less than 40 mg/dL and greater than 400 mg/dL. For those samples less than 40 mg/dL and greater than 400 mg/dL, a pooled capillary whole blood sample was used instead and spiked to the desired level. The subject device was compared to the YSI.

Difference distribution for glucose concentration<75mg/dL compared to YSI			
Difference	Difference	Difference	
within ±5mg/dL	within ±10mg/dL	within ±15mg/dL	
67% (24/36)	89% (32/36)	100% (36/36)	
Difference distribution for glucose concentration • 75mg/dL compared to YSI			
Difference	Difference	Difference	Difference
within ±5 %	within ±10 %	within ±15 %	within ±20 %
121/164 (74%)	147/164 (90%)	162/164 (99%)	162/164 (99%)

The applicant states the data falls within ISO 15197 criteria

Device	TD-4277
Y	0.9765x + 3.3248
R	0.9798
N	200
Range	35.75-466.5 mg/dL

Lay User Study

One hundred and fifty (150) male and female subjects representing typical age ranges and education of predominantly of high school and below, who were able to read the English user manuals, were enrolled in this study at three sites. Test results obtained from lay users are compared to YSI 2300 below.

Difference distribution for glucose concentration<75mg/dL compared to YSI			
Difference	Difference	Difference	
within ±5mg/dL	within ±10mg/dL	within ±15mg/dL	
13/24(54%)	20/24(83%)	24/24(100%)	
Difference distribution for glucose concentration ≥ 75mg/dL compared to YSI			
Difference	Difference	Difference	Difference
within ±5 %	within ±10 %	within ±15 %	within ±20 %
37/126(29%)	64/126(49%)	92/126(75%)	120/126(95%)

Comparison	N	Slope and y-intercept	R^2
Lay user vs. YSI-2300	150	y = 1.0488x + 1.5456	0.9743
Professional vs. YSI-2300	150	y = 1.0589x - 2.2164	0.9765

A survey for the ease of use of the TD-4277 meter was carried out by providing subjects with questionnaires for rating the ease of understanding of the instructions and overall ease of use of the device after they finished the blood glucose tests. 100% of the users had above 3 (neutral) in average rating with a scale of 1-5 for ease of use of the device.

b. Matrix comparison:

The blood glucose measurement accuracy of the proposed device with venous samples was evaluated. Fresh venous whole blood samples were tested using both TD-4277 and the reference method, YSI-2300 glucose analyzer.

One hundred (100) samples from 24.5-579 mg/dL were included. The fresh venous whole blood samples were from different individuals except those with blood glucose concentration less than 40 mg/dL and greater than 400 mg/dL. For those samples less than 40 mg/dL and greater than 400 mg/dL, a pooled venous whole blood sample was used instead and spiked to the desired level as in the above matrix comparison distribution of samples.

Difference distribution for glucose concentration<75mg/dL compared to YSI			
Difference	Difference	Difference	
within ±5mg/dL	within ±10mg/dL	within ±15mg/dL	
80% (16/20)	80% (16/20)	95% (19/20)	
Difference distribution for glucose concentration ≥ 75mg/dL compared to YSI			
Difference	Difference	Difference	Difference
within ±5 %	within ±10 %	within ±15 %	within ±20 %
43%(34/80)	(80%(64/80)	93%(74/80)	95%(76/80)

The applicant states the data falls within ISO 15197 criteria

Device TD-4277
Y 1.0106x + 4.2515
R^2 0.9899
N 100
Range 24.3-579 mg/dL

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):
      Not Applicable

4. Clinical cut-off:
   Not Applicable

5. Expected values/Reference range:

Reference values:

Time of day	Normal plasma glucose range for people without diabetes
Fasting and before meal	Less than 100 mg/dL (5.6 mmol/L)
2 hours after meals	Less than 140 mg/dL (7.8 mmol/L)

Source: American Diabetes Association (2008). Clinical Practice Recommendations. Diabetes Care, 31 (Supplement 1): S1-108.

N. Instrument Name:

TD-4277 Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

   Does the applicant's device contains the ability to transmit data to a computer, webserver, or mobile device?:

   Yes _X___ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?:

   Yes _____ or No _X___

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ____X___ or No _____

3. Specimen Identification:

   Time, date and mode of testing (general, post meal, 8 hours with no food intake and control solutions)

4. Specimen Sampling and Handling:

   Fingerstick capillary and venous blood samples, but lay user may not test venous blood samples.

5. Calibration:

   One code function (No Code)

6. Quality Control:

   The meter stores QC results on the meter

   Control material is included in the meter kit and the three levels are available separately and instructions are provided as to when control testing should be done.

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

The data management software used to acquire the data from the proposed device was cleared, under k070941. Ease of use in data transmission from a blood glucose meter to a PC has been validated in both the submissions of the data management software and the predicate device, FORA G30 BLOOD GLUCOSE MONITORING SYSTEM (K090187) and the method of setting up and transmission in the subject device are the same as the predicate device. The sponsor provided an acceptable report for the data accuracy for change from RS-232 to USB connection.

The sponsor conducted the FleschKincaid readability assessment of the User Manual and obtained a grade level score equivalent to an average student in 8th grade reading level. The test strip and control solution package inserts have a 7th grade reading level.

Hematocrit Study:
To test accuracy due to the hematocrit effect, venous blood samples were collected in an anti-coagulant (Li-EDTA) vacuum tube, and glucose levels were adjusted to the following ranges; 10-20 mg/dL, 20-50 mg/dL, 50-100 mg/dL, 100-200 mg/dL, 200-350 mg/dL, 350-450 mg/dL, 450-550 mg/dL, and 600-700 mg/dL. Samples were then adjusted to hematocrit levels of 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, and 65%. The YSI 2300 was used as the reference method. The results of the hematocrit study were reviewed and found to be acceptable for 20% to 60% hematocrit.

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.