

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

A. 510(k) Number:

k090187

B. Purpose for Submission:

Clearance of a new device

C. Measurand:

Whole blood glucose

D. Type of Test:

Whole blood glucose concentration through a quantitative amperometric assay (Glucose Oxidase)

E. Applicant:

Taidoc Technology Corporation

F. Proprietary and Established Names:

FORA G30 Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1345, Blood Glucose Test System
2. Classification:
Class II
3. Product code:
NBW, CGA
4. Panel:
75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):
See indications for use below.
2. Indication(s) for use:
The FORA G30 Blood glucose monitoring system is 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. 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.

The alternative site testing in the FORA G30 Blood glucose monitoring system can be used only during steady-state blood glucose conditions.

3. Special conditions for use statement(s):

- Not intended for diagnosis of diabetes mellitus
- Not intended for use on neonates
- For *in vitro* diagnostic use only
- Not for use on critically ill patients, dehydrated patients or hyperosmolar patients

4. Special instrument requirements:

FORA G30 Blood Glucose Monitoring System

I. Device Description:

The FORA G30 Blood Glucose Monitoring System consists of a meter and test strips. The system utilizes an electrochemical method-based meter and dry reagent biosensor (test strips) for blood glucose testing, using the glucose oxidase enzyme. Control solutions were previously cleared under k041107.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Clever Chek TD-4230 Blood Glucose Monitoring System

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

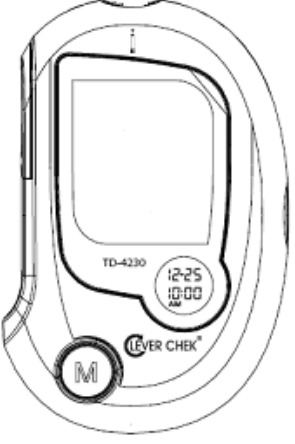
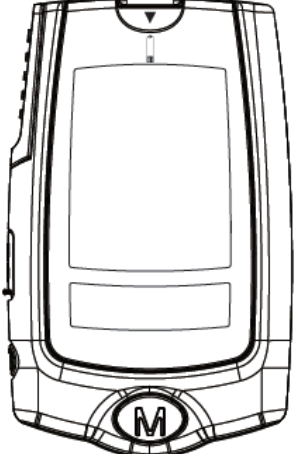
k070472

3. Comparison with predicate:

Similarities		
Item	Predicate Device	Candidate Device
Intended Use	The Clever Chek TD-4230 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in whole blood taken from the finger, the palm, the forearm, the upper arm, the calf, and the thigh. They are intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. They are not intended for the diagnosis of or screening for diabetes mellitus, and are not intended for use on neonates.	The FORA G30 Blood glucose monitoring system is 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. 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

Similarities		
Item	Predicate Device	Candidate Device
		neonates. The alternative site testing in the FORA G30 Blood glucose monitoring system can be used only during steady-state blood glucose conditions.
Detection Method	Amperometry: measuring a current produced by a chemical reaction	Amperometry: measuring a current produced by a chemical reaction
Enzyme	Glucose Oxidase	Glucose Oxidase
Temperature Compensation	Automatic compensation with built-in thermister	Automatic compensation with built-in thermister
Measurement Range	20 – 600 mg/dL	20 – 600 mg/dL
Operating Condition	10°C – 40°C, Below 85% R.H.	10°C – 40°C, Below 85% R.H.
Strip Vial Opened Use Time	90 days	90 Days
Memory Feature	450 measurements with day and time	450 measurements with day and time
Auto Shut Off (min)	3	3
Alarm	Beeping sound and/or error message in LCD display	Beeping sound and/or error message in LCD display
Power	One CR2032 battery	One CR2032 battery

Differences		
Item	Predicate Device	Candidate Device
Meter Size (mm)	94 x 20 x 48	85 x 52 x 15
Weight (g)	79.22	52.0
Sample Volume (µL)	0.7	0.5
Reaction Time (sec)	7	5
Test Strip Calibration	Select code number from the meter	One code function
Test Strip Size (mm)	33 (L) x 9 (W) x 0.72 (H)	36 (L) x 8.5 (W) x 0.15 (H)
Test Strip Chemical Components	<ul style="list-style-type: none"> - Glucose oxidase (A. niger) 10 % - Electron shuttle 50% - Enzyme protector 8% - Non-reactive ingredients 32% 	<ul style="list-style-type: none"> - Glucose oxidase (A. niger) 13 % - Electron shuttle 39% - Enzyme protector 6% - Non-reactive ingredients 42%

Differences		
Item	Predicate Device	Candidate Device
Appearance		

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. Version - 2003(E). May 1, 2003.
- ISO 14971 – Medical devices – Application of risk management to medical devices, 1st edition, 2000
- CLSI EP9-A - Method comparison and bias estimation using patient samples. Version - Vol.15, No.17. 1995.
- CLSI EP5-A - Evaluation of precision performance of clinical chemistry devices: Version - Vol.19, No.2. 1999.
- CLSI EP6-A - Evaluation of the linearity of quantitative analytical methods; proposed guideline – second edition
- CLSI EP7-A - Interference testing in clinical chemistry.
- Arch. Pathology Laboratory Medicine – Effects of different hematocrit levels on glucose measurements with handheld emters for point-of-care testing. Volume 124, August 2000
- EN 13640:2002 – Stability testing of in vitro diagnostic medical devices
- IEC 61010-1:2001 – Safety requirements for electrical equipment for measurements, control, and laboratory use – part 1: general requirement
- IEC 60601-1:1988 – Medical Electrical Equipment – Part 1: General requirements for safety

L. Test Principle:

The FORA G30 Blood Glucose Monitoring System uses electrochemical methodologies. The system quantitatively measures blood glucose level using an amperometric method, which involves detecting the current produced from glucose oxidation. The electrons generated during this reaction are transferred from the blood to the electrodes. The magnitude of the resultant current is proportional to the concentration of glucose in the specimen and the signal is converted into a readout displayed on the meter.

M. Performance Characteristics (if/when applicable):1. Analytical performance:*a. Precision/Reproducibility:*

The sponsor's precision studies were based on ISO 15197 and CLSI EP5-A recommendations. The within-run precision study samples used were venous blood (hematocrit range 38% - 54%) spiked with dextrose to create 5 levels of blood glucose. Three lots of test strips and 10 meters were used in the study, with 10 tests performed on each meter for a total of 100 tests per blood glucose level.

The results are as follows:

Samples	No. of Tests	Average (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
Level 1	100	42.7	1.76	4.11
Level 2	100	78.9	3.23	4.10
Level 3	100	152.2	3.54	2.33
Level 4	100	203.8	4.63	2.27
Level 5	100	305.7	7.13	2.33

The day-to-day run precision study samples used were glucose control solutions. Low, medium, and high levels were used. Three lots of test strips and 10 meters were used in the study, with 1 test performed on each meter per day for 10 days, for a total of 100 tests per control level.

The results are as follows:

Samples	No. of Tests	Average (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
Low Control	300	82.7	2.51	3.04
Medium Control	300	145.1	3.09	2.13
High Control	300	334.9	5.40	1.61

b. Linearity/assay reportable range:

The sponsor indicated that the linearity study protocol was developed according to CLSI EP6-A. The candidate device was tested to verify linearity of the system using blood samples with glucose concentrations between 20-600 mg/dL. Venous blood samples were used. Samples were spiked with dextrose in order to create nine glucose levels (20, 40, 60, 90, 120, 200, 320, 420, 600 mg/dL). Testing was performed using the FORA G30 meter (candidate device) and the YSI-2300 glucose

analyzer (reference method). Two lots of test strips were used in the study with 5 tests per lot performed on each meter, for a total of 10 tests per blood glucose level.

The stated reportable range of the meter is 20-600 mg/dL

The results are as follows:

Linear Regression	Correlation coefficient (R^2)
$y = 0.9819x + 1.9316$	0.9997

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

The FORA G30 system (including meter and test strips) has an operating environment of 10 – 40°C and relative humidity below 85%. Performance testing supports this range. The system was also tested in extreme conditions to determine if it could operate correctly in its indicated range after being exposed to harsher conditions. Temperature exposure limits of the system were determined to be -20 – 60°C, and humidity exposure limits of 5 - 95% relative humidity. Drop tests and vibration tests were also performed on the device.

Test strips were examined using accelerated stability studies to determine unopened shelf life. The sponsor currently has real time stability testing to support unopened shelf life of the test strips for 12 months when stored between 4 – 40°C. In-use stability of the test strips is 90 days after the first opening.

In-use stability of the glucose control solution (cleared under k041107) is 90 days after the first opening when stored between 2 – 30°C.

d. Detection limit:

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

e. Analytical specificity:

Interference Study:

The sponsor indicated that the interference study protocol was developed according to CLSI EP7-A. Blood samples were collected in an anti-coagulant (Li-EDTA) vacuum tube from seven volunteers, and glucose levels were adjusted to a low (75-85 mg/dL) and a high (300 mg/dL) level using the YSI 2300 as a reference instrument. The percent bias caused by various interferences must be less than $\pm 10\%$. Interferents causing a bias greater than 10% are examined using a dose-response test to interpolate the concentration at which 10% bias would be observed.

The results are as follows:

<i>Exogenous substance</i>			<i>Concentration at which drug interference was observed</i>	
Therapeutic levels		Maximum Test concentration	At low glucose level	At high glucose level
Acetaminophen (mg/dL)	1-2	25	10	10
Ascorbic acid (mg/dL)	0.8-1.2	4	3	3
Dopamine (mg/dL)	0.4-1.6	6.25	No interference up to test concentration	
L-Dopa (mg/dL)	0.02-0.3	3	No interference up to test concentration	1.5
Methyl Dopa (mg/dL)	0.1-0.5	1.5	1.5	1.5
Tolbutamide (mg/dL)	5.3-10	64	No interference up to test concentration	
<i>Endogenous substance</i>			<i>Concentration at which drug interference was observed</i>	
Physiological levels		Maximum Test concentration	At low glucose level	At high glucose level
Uric acid (mg/dL)	7	10	10	10
Triglyceride (mg/dL)	190	2000	No interference up to test concentration	

Altitude Study:

An altitude study was performed on a mountain in Wuling, Taiwan with an elevation of 10,744 ft. The capillary blood glucose results of 20 volunteers were tested using the FORA G30 meter at high altitude and compared to the Roche Accu-Chek meter at high altitude. The results of this study are acceptable: 95% of the measurements must have a deviation less than 20% at ≥ 75 mg/dL and less than 15 mg/dL at < 75 mg/dL.

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; 40-60 mg/dL, 70-120 mg/dL, 120-200 mg/dL, 240-280 mg/dL, and 420-440 mg/dL and 480-520 mg/dL. Samples were then adjusted to hematocrit levels of 20%, 30%, 40%, 50%, and 60%. The YSI 2300 was used as the reference method.

The results of the hematocrit study were reviewed and found to be acceptable.

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

2. Comparison studies:

a. *Method comparison with predicate device:*

Reference Method Comparison:

This study was performed in accordance with CLSI EP9-A and ISO 15197. Three clinical sites were used with 122 total patients (with samples ranging from 35 to 522 mg/dL). Samples below 40 mg/dL were obtained by allowing patient samples to glycolize, and then spiked to the appropriate level. Samples above 400 mg/dL were spiked. Health care professionals tested capillary whole blood using the FORA G30 (the candidate device) and the YSI 2300 (the reference method) and each site met the ISO 15197 standard where ninety-five percent (95%) of the individual glucose results shall fall within ± 15 mg/dL of the results at glucose concentrations < 75 mg/dL and within $\pm 20\%$ at glucose concentrations ≥ 75 mg/dL.

The results are as follows:

Glucose Concentrations < 75 mg/dL:

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
89% (16/18)	100% (18/18)	100% (18/18)

Glucose Concentrations ≥ 75 mg/dL:

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
62% (64/104)	94% (98/104)	97% (101/104)	99% (103/104)

Linear Regression Analysis:

Site#	Comparison	N	Slope and y-intercept	r
1	FORA G30 vs. YSI-2300	41	$y = 1.007x + 0.570$	0.990
2	FORA G30 vs. YSI-2300	41	$y = 0.980x + 3.635$	0.990
3	FORA G30 vs. YSI-2300	40	$y = 1.000x + 2.740$	0.993
total	FORA G30 vs. YSI-2300	122	$y = 0.994x - 2.576$	0.991

A Clarke error grid analysis was also presented; 99% (121/122) of results fall in zone A – *clinically accurate*. 1% (1/122) fall in zone B - *deviating from the reference method by more than 20% but would lead to benign or no treatment*.

Lay-User Study:

The study was performed in accordance with CLSI EP9-A and ISO 15197. 128 lay users at 3 different sites tested themselves once with the FORA G30 blood glucose meter. Lay users were given the user manual in English, and were given no additional instructions. Health care professionals then took one further measurement with the FORA G30 blood glucose meter, and the results between the lay users and health care professionals were compared.

The results are as follows:

Glucose Concentrations < 75 mg/dL:

Within \pm 5 mg/dL	Within \pm 10 mg/dL	Within \pm 15 mg/dL
54% (14/26)	81% (21/26)	100% (26/26)

Glucose Concentrations \geq 75 mg/dL:

Within \pm 5%	Within \pm 10%	Within \pm 15%	Within \pm 20%
47% (48/102)	71% (72/102)	86% (88/102)	95% (97/102)

Linear Regression Analysis:

Site#	Comparison	N	Slope and y-intercept	r
1	FORA G30 vs. YSI-2300	41	$y = 1.034x - 2.115$	0.988
2	FORA G30 vs. YSI-2300	42	$y = 1.027x - 3.809$	0.974
3	FORA G30 vs. YSI-2300	45	$y = 0.970x - 1.250$	0.9621
total	FORA G30 vs. YSI-2300	128	$y = 1.001x - 1.503$	0.972

A Clarke error grid analysis was also presented; 96% (123/128) of results fall in zone A – *clinically accurate*. 4% (5/128) fall in zone B - *deviating from the reference method by more than 20% but would lead to benign or no treatment*.

Predicate Device Comparison:

This study was performed in accordance with CLSI EP9-A and ISO 15197. YSI 2300 was used as the reference method. Three clinical sites were used with 136 total patients (with samples ranging from 24 to 594 mg/dL). Samples < 40 mg/dL were obtained by allowing patient samples to glycolize, and are then spiked to the appropriate level. Samples > 400 mg/dL were spiked. Health care professionals tested capillary whole blood using the FORA G30 (the candidate device) and the Clever Chek TD-4230 (the predicate device) and each site met the ISO 15197 standard where ninety-five percent (95%) of the individual glucose results shall fall within ± 15 mg/dL of the results at glucose concentrations < 75 mg/dL and within $\pm 20\%$ at glucose concentrations ≥ 75 mg/dL.

The results are as follows:

Glucose Concentrations < 75 mg/dL:

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
FORA G30	89% (16/18)	100% (18/18)	100% (18/18)
Clever Chek TD-4230	94% (17/18)	100% (18/18)	100% (18/18)

Glucose Concentrations ≥ 75 mg/dL:

	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
FORA G30	62% (64/104)	94% (98/104)	97% (101/104)	99% (103/104)
Clever Chek TD-4230	61% (63/104)	95% (99/104)	98% (102/104)	99% (103/104)

Linear Regression Analysis:

Comparison	N	Slope and y-intercept	r
FORA G30 vs. YSI-2300	122	$y = 0.994x - 2.576$	0.991
Clever Chek TD-4230 vs. YSI-2300	122	$y = 0.971x + 4.402$	0.988

A Clarke error grid analysis was also presented; 99% (121/122) of results fall in zone A – *clinically accurate*. 1% (1/122) fall in zone B - *deviating from the reference method by more than 20% but would lead to benign or no treatment*. These results are the same for both the FORA G30 and the Clever Chek TD-4230.

Alternate Site Testing Comparison:

This study was performed in accordance with NCCLS EP9-A and ISO 15197. 120 lay users at 3 different locations tested themselves using each alternate site with the FORA G30 blood glucose meter. Lay users were given the user manual in English, and were given no additional instructions. The lay user then obtained a fingertip blood sample, and the fingertip glucose result was compared to the AST glucose result.

The results are as follows:

Glucose Concentration < 75 mg/dL:

AST Sites	Difference within $\pm 5\text{mg/dL}$	Difference within $\pm 10\text{mg/dL}$	Difference within $\pm 15\text{mg/dL}$
Palm	41%(11/27)	93%(25/27)	100%(27/27)
Forearm	67%(18/27)	96%(26/27)	96%(26/27)
Upper arm	59%(16/27)	89%(24/27)	100%(27/27)
Calf	48%(13/27)	85%(23/27)	96%(26/27)
Thigh	37%(10/27)	85%(23/27)	100%(27/27)

Glucose Concentration ≥ 75 mg/dL:

AST Sites	Difference within $\pm 5\%$	Difference within $\pm 10\%$	Difference within $\pm 15\%$	Difference within $\pm 20\%$
Palm	56%(52/93)	84%(78/93)	96%(89/93)	100%(93/93)
Forearm	34%(32/93)	61%(57/93)	86%(80/93)	98%(91/93)
Upper arm	39%(36/93)	77%(72/93)	90%(84/93)	99%(92/93)
Calf	24%(22/93)	72%(67/93)	89%(83/93)	97%(90/93)
Thigh	26%(24/93)	57%(53/93)	84%(78/93)	98%(91/93)

Linear Regression Analysis:

Comparison	Range (mg/dL)	Slope and y-intercept	R square
Palm vs. finger	40-425	$y = 0.979x + 4.0608$	0.9866
Forearm vs. finger	40-425	$y = 1.002x + 2.3467$	0.9708
Upper arm vs. finger	40-425	$y = 1.016x + 0.1852$	0.9789
Calf vs. finger	40-425	$y = 0.952x + 6.3207$	0.9745
Thigh vs. finger	40-425	$y = 0.953x + 4.8445$	0.9661

The results of a Clarke error grid analysis are presented below; zone A – *clinically accurate*, zone B - *deviating from the reference method by more than 20% but would lead to benign or no treatment*.

Zone	Palm vs. finger	Forearm vs. finger	Upper arm vs. finger	Calf vs. finger	Thigh vs. finger
A	100% (120/120)	98% (117/120)	99% (119/120)	97% (116/120)	98% (118/120)
B	0	2% (3/120)	1% (1/120)	3% (4/120)	2% (2/120)
C	0	0	0	0	0
D	0	0	0	0	0
E	0	0	0	0	0

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):

Not Applicable.

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

The sponsor included the following expected glucose values for people without diabetes in their user manual:

Fasting and before meals: 70 – 110 mg/dL (3.9 mmol/L – 6.1 mmol/L) ¹

Two hours after meals: less than 140 mg/dL (7.8 mmol/L) ²

Measurement result at any time of day without regard to time since last meal should be less than 200 mg/dL. ³

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

²⁾ ADA Clinical Practice Recommendations 2003.

³⁾ Diabetes Care, volume 28, supplement 1, January 2005.

N. Instrument Name:

FORA G30 Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:

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

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

Yes ___X___ (reviewed under k070941) or No _____

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

Yes ___X___ or No _____

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:

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, which can be applied directly to the test strip.

5. Calibration:

The device is designed to be used with Taidoc Technology Corporation's "no coding" test strips. These strips are identified with a "38" printed on the test strip vial as the lot code. Other types of test strips should not be used with the device. No further calibrations are required of the user.

6. Quality Control:

The sponsor has three levels of controls available for this meter. A normal control is supplied with the device, but low and high levels must be purchased separately. When a test strip is inserted into the meter, a control can be run by pushing the "QC" button. An acceptable range for each control level is printed on the test strip vial label.

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

None.

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.