

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

**A. 510(k) Number:**

k143467

**B. Purpose for Submission:**

New device

**C. Measurand:**

Capillary whole blood glucose from the fingertip, palm, forearm, and upper arm

**D. Type of Test:**

Quantitative amperometric assay, glucose dehydrogenase (GDH-FAD)

**E. Applicant:**

TaiDoc Technology Corporation

**F. Proprietary and Established Names:**

FORA GD43 Blood Glucose Monitoring System

**G. Regulatory Information:**

1. Regulation section:

21 CFR 862.1345, Glucose test system

2. Classification:

Class II

3. Product code:

NBW, System, Test, Blood Glucose, Over the Counter  
LFR, Glucose Dehydrogenase, Glucose

4. Panel:

Clinical Chemistry (75)

**H. Intended Use:**

1. Intended use(s):

See Indications for Use below.

2. Indications(s) for use:

The FORA GD43 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the

fingertip and alternative sites (palm, forearm and upper arm). This blood glucose monitoring system is intended to be used by a single person and should not be shared. Alternative site testing (AST) should only be done during steady-state times (when glucose is not changing rapidly).

The FORA GD43 Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor for use on neonates.

The FORA GD43 Test Strips are for use with the FORA GD43 Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood from the fingertip and alternative sites (palm, forearm and upper arm).

3. Special conditions for use statement(s):

- For in vitro diagnostic use only
- Not for use in diagnosis or screening of diabetes mellitus
- Not for neonatal use
- Not for use on patients who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.
- Not for use in critically ill patients
- Alternative site testing (AST) should only be done during steady-state times (when glucose is not changing rapidly)
- Alternative site testing results should not be used to calibrate continuous glucose monitors (CGMs)
- Alternative site testing results should not be used in insulin dosing calculations

4. Special instrument requirements:

FORA GD43 Blood Glucose Meter

**I. Device Description:**

The FORA GD43 Blood Glucose Monitoring System consists of the FORA GD43 Blood Glucose Meter, Owner's Manual, Protective Wallet, Quick Start User Guide, Daily Log Book, Warranty Card and 2 x 1.5 V AAA alkaline batteries. The FORA GD43 Test Strips are for use with the FORA GD43 Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood from the fingertip and alternative sites (palm, forearm and upper arm). The FORA GD43 Test Strips need to be purchased separately.

The control solutions to be used with the FORA GD43 System are the FORA Control Solutions, cleared in k093724. Three levels are available: Level 1, Level 2, and Level 3. Level 1 is included in some kit configurations and all levels can be purchased separately. The Clever Chek Health Care System Software is an optional software accessory for use with the FORA GD43 Blood Glucose Monitoring System, which provides enhanced data management capabilities.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
FORA GD40 Blood Glucose Monitoring System
2. Predicate 510(k) number(s):  
k101509
3. Comparison with predicate:

<b>Similarities</b>		
	Predicate FORA GD40 Blood Glucose Monitoring System (k101509)	Candidate FORA GD43 Blood Glucose Monitoring System (k143467)
Indications for Use/Intended Use	To quantitatively measure glucose (sugar) in whole blood, as an aid in monitoring the effectiveness of glucose control.	Same
Enzyme	Glucose Dehydrogenase (GDH-FAD)	Same
Test Method	Amperometric detection	Same
Measuring Range	20-600 mg/dL	Same
Reaction time	5 sec	Same
Memory Capacity	1000 data points	Same
Dimensions	110.0 L/57.0 W/25.0 H (mm)	Same
Weight	71g without battery	Same

<b>Differences</b>		
	Predicate FORA GD40 Blood Glucose Monitoring System (k101509)	Candidate FORA GD43 Blood Glucose Monitoring System (k143467)
Sample type	Capillary whole blood from finger	Capillary whole blood from fingertip, palm, forearm, and upper arm
Electrode	carbon	gold
Sample volume	1.1uL	0.5uL
Hematocrit range	20-60%	20-70%
Test Strip stability	Opened - 3 months Unopened - 18 months	Opened - 24 months Unopened - 24 months
Operating conditions	50°F - 104°F (10°C - 40°C)	46.4°F - 113°F (8°C - 45°C)

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

- ISO 14971: Medical Devices - Application of risk management to medical devices

- IEC 62304: Medical device software - Software lifecycle processes
- IEC 61010-1, Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- IEC 61010-2, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- IEC 61326-1, Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
- IEC 61326-2-6, Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment
- IEC 60601-1-2, Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests
- CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline.
- CLSI EP7-A2, Interference Testing in Clinical Chemistry; Approved Guideline.
- CLSI EP6-P, Evaluation of the Linearity of Quantitative Analytical Methods

**L. Test Principle:**

The test is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter utilizes the current signal to calculate the blood glucose level.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

*a. Precision/Reproducibility:*

Repeatability studies (within-day precision) were performed with venous whole blood samples at five glucose concentration ranges (30-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, 251-400 mg/dL) using 3 test strip lots. Ten runs were performed on each sample across the three test strip lots with 10 replicates per run resulting in a total of 100 replicates collected for each glucose level. Results are summarized below:

Glucose Level	30-50 (mg/dL)			51-110 (mg/dL)			111-150 (mg/dL)		
	1	2	3	1	2	3	1	2	3
Test Strip Lot									
Mean (mg/dL)	44.3	45.4	44.7	84.4	85.3	84.7	132.7	136.8	134.8
SD	1.60	1.33	1.48	1.99	2.36	1.94	3.04	3.64	3.71
CV%	3.61	2.93	3.32	2.36	2.77	2.29	2.29	2.66	2.75
N	30	30	40	30	30	40	30	30	40

Glucose Level	151-250 (mg/dL)			251-400 (mg/dL)		
	1	2	3	1	2	3
Test Strip Lot						
Mean (mg/dL)	199.7	199.2	199.1	357.8	365.7	360.7
SD	4.83	4.96	4.94	11.53	13.90	13.67
CV%	2.42	2.49	2.48	3.22	3.80	3.79
N	30	30	40	30	30	40

Intermediate precision (day-to-day precision) was evaluated using three glucose control solutions. Ten strip vials, from three test strip lots, were assigned to each of the three control levels (30-50mg/dL, 96-144 mg/dL, 280-420 mg/dL). From each strip vial, a test was performed on each of the 3 control level solutions for 10 days. A total of 10 replicates were collected per glucose level tested per day for a total of 100 measurements per glucose level tested across the three test strip lots. Results are summarized below:

Glucose Level	Level 1 (30-50 mg/dL)			Level 2 (96-144 mg/dL)			Level 3 (280-420 mg/dL)		
	1	2	3	1	2	3	1	2	3
Test Strip Lot									
Mean (mg/dL)	44.3	44.8	44.9	133.7	137.3	135.3	338.1	344.1	341.9
SD	1.46	1.24	1.49	2.31	2.52	2.93	5.20	4.92	5.24
CV%	3.30	2.77	3.32	1.73	1.84	2.17	1.54	1.43	1.53
N	30	30	40	30	30	40	30	30	40

*b. Linearity/assay reportable range:*

Linearity was evaluated using 3 test strip lots and 10 venous blood samples ranging in glucose concentrations from 12 to 654 mg/dL (12, 35, 77, 113, 189, 274, 369, 453, 565, and 654 mg/dL). Three runs were performed on each sample, on each strip lot, with replicates of 5 for each run and test strip lot resulting in a total of 15 replicates for each test strip lot and glucose level tested. The values from the FORA GD43 meter were compared with those obtained from the reference method. The results from regression analysis are summarized below:

$$\text{Lot \#1: } y=1.0059 x - 0.091; R^2 = 0.9983$$

$$\text{Lot \#2: } y=1.0167 x - 0.5132; R^2 = 0.9982$$

$$\text{Lot \#3: } y=1.0106 x - 1.4375; R^2 = 0.9980$$

The results of the study support the sponsor's claimed glucose measurement range of 20 to 600 mg/dL.

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

*Traceability:* According to the sponsor, the FORA GD43 system is traceable to the NIST SRM 917 glucose reference material. A method comparison was performed using the candidate device and the YSI-2300 analyzer as the reference method (see Section 2.a.)

*Value Assignment for Control Solutions:* Established in k093724.

*Control Solution Stability:* Protocols and acceptance criteria for open vial and closed vial (shelf-life) stability for the control solutions and linearity set solutions were previously reviewed and found to be acceptable under k093724. The sponsor claims 24 month shelf life stability and 3 month open-vial stability when stored at the recommended storage temperatures of 39°F to 86°F (4°C to 30°C).

*Test Strip Stability:* The protocols and acceptance criteria for the FORA GD43 test strips were reviewed and found to be acceptable. The sponsor claims closed-vial (shelf life) and open-vial stability of 24 months when stored at 35.6-86°F (2-30°C) and 10-90% RH.

*d. Detection limit:*

The reportable range for the FORA GD43 Blood Glucose Monitoring System is 20 to 600 mg/dL. This range was verified by the linearity study (M.1.b).

*e. Analytical specificity:*

To assess potential interference the sponsor used venous whole blood samples adjusted to 2 different glucose levels of 75 and 330 mg/dL, split into a control sample and a test sample. Various endogenous and exogenous substances were then added to the test sample only. The % difference between the test and control sample was calculated and highest concentration tested at which no significant interference was observed is presented in the table below:

<b>Potential Interfering Substance</b>	<b>Concentration at which no significant interference is observed (mg/dL)</b>	<b>Potential Interfering Substance</b>	<b>Concentration at which no significant interference is observed (mg/dL)</b>
Acetylsalicylic acid	50	Icodextrin	2000
Acyclovir	3.1	Isomalt	1000
Allopurinol	5	Lactose	1000
Amitriptylline	0.25	Lactitol	1000
Amoxicillin	11	Lidocaine	6
Ampicillin	5	Magnesium	5 mM
Aspirin (salicylic acid)	60	Maltitol	1000
Atenolol	10	Maltose	1000
Bicarbonate	336 mM	Metaproterenol	1.81

Bile acids	6	Metformin HCl	50
Bilirubin	40	Metoprolol	0.3
Caffeine	10	Naproxen	100
Calcium	5 mM	Nifedipine	0.17
Ceftriazone	250	Nortriptyline	0.15
Chloride	140 mM	Penicillin	12
Cholesterol	500	Phenytoin	10
Clonidine	2	Piroxicam	5
Creatinine	30	Potassium	10 mM
Digoxin	0.16	Sodium	200 mM
Diphenhydramine	1	Sorbitol	1000
Enalapril	0.15	Sulfamethoxazole	120
Ephedrine HCl	50	Sulfate	5 mM
Erythromycin	20	Terfenadine	0.45
Estrone	0.1	Tetracycline	10
Famotidine	0.13	Theophylline	25
Fluoxetine	0.8	Tolbutamide	64
Folic acid	13.3	Total Protein (gamma globulin)	12000
Fructose	1000	Trimopna	12.5
Furosemide	2	Xylitol	1000
Galactose	1000	Urea	600
Gentisic acid	2	Vancomycin	25
Glyburide	1.07	Verapamil	0.45
Glycerol	1000	Vitamin E	20
Hemoglobin	500	Warfarin	2
Ibuprofen	55		

The following substances had interference above the concentrations stated:

<b>Interfering Substance</b>	<b>Concentration threshold for interference (mg/dL)</b>	<b>Interfering Substance</b>	<b>Concentration threshold for interference (mg/dL)</b>
Acetaminophen	20	Uric acid	10
Ascorbic acid	5.0	Mannitol	5000
Dopamine	2.5	Mannose	200
L-Dopa	2.1	Xylose	5.0
Methyldopa	1.25	Triglycerides	3000
Tolazamide	20		

In addition, Glutathione and Pralidoxime Iodide may produce elevated glucose within the therapeutic or physiologic concentration.

The sponsor has the following limitations in their labeling:

- Exogenous substances: Dopamine, L-Dopa, methyldopa, tolazamide, ascorbic acid (vitamin C), acetaminophen and mannose may cause inaccurate results if concentrations of these substances is greater than therapeutic/physiologic concentrations.
- Endogenous substance: Uric acid may cause inaccurate results if concentration of the substance greater than therapeutic/physiologic concentration.
- Xylose: Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can give falsely elevated results.
- Mannitol: Up to 5000 mg/dL do not affect the results significantly, but may cause inaccurate results at higher level.
- Lipemic Effects: Blood triglycerides up to 3000 mg/dL do not affect the results significantly, but may affect results at higher level.
- Glutathione reduced and pralidoxime iodide: Do not test blood glucose during or soon after a glutathione reduced or pralidoxime iodide treatment. The two compounds within the therapeutic/physiologic concentration range (Glutathione: 47 – 100 mg/dL; Pralidoxime iodide: ~ 10 mg/dL) may affect the glucose results.

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

2. Comparison studies:

*a. Method comparison with predicate device:*  
See Section 3.c. below.

*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):*

**User Performance Study:**

To assess the performance of the FORA GD43 Blood Glucose Monitoring System in the hands of lay users, the sponsor conducted a study with 150 lay user participants at 3 hospitals. All lay user participants collected and tested their own finger stick samples as well as their own samples from each alternative site. Another blood sample from each lay user was also collected by a technician and measured on YSI 2300 reference analyzer. 150 results (from natural and altered samples) ranged from 40 to 556 mg/dL were obtained per collection site. Results obtained by lay users are presented below:

For glucose concentrations <75 mg/dL

site	Within $\pm$ 5 mg/dL	Within $\pm$ 10 mg/dL	Within $\pm$ 15 mg/dL
Fingertip	57.7% (15/26)	96.2% (25/26)	100% (26/26)
Palm	53.8% (14/26)	88.5% (23/26)	100% (26/26)
Forearm	53.8% (14/26)	84.6% (22/26)	100% (26/26)
Upper arm	46.2% (12/26)	76.9% (20/26)	100% (26/26)

For glucose concentrations  $\geq$  75 mg/dL

Site	within $\pm$ 5%	within $\pm$ 10%	within $\pm$ 15%	within $\pm$ 20%
Fingertip	53.2% (66/124)	76.6% (95/124)	96.0% (119/124)	100% (124/124)
Palm	41.9% (52/124)	80.6% (100/124)	95.2% (118/124)	100% (124/124)
Forearm	40.3% (50/124)	81.5% (101/124)	95.2% (118/124)	100% (124/124)
Upper arm	39.5% (49/124)	76.6% (95/124)	95.2% (118/124)	100% (124/124)

Regression Analysis Results: Lay-user vs reference method:

Site	slope	95% CI of slope	intercept	95% CI of intercept	R <sup>2</sup>
Fingertip	0.9867	0.9661~1.0072	2.3097	-1.7874~6.4068	0.9838
Palm	0.9907	0.9685~1.0130	0.8984	-3.5421~5.3389	0.9812
Forearm	0.9883	0.9658~1.0107	1.5578	-2.9178~6.0334	0.9808
Upper arm	0.9962	0.9746~1.0179	2.7011	-1.6154~7.0175	0.9824

4. Clinical cut-off:  
Not Applicable

5. Expected values/Reference range:

Time of day	People without diabetes
Fasting and before meals	<100 mg/dL
2 hours after meals	<140 mg/dL

American Diabetes Association (2014), Clinical Practice Recommendations, Diabetes Care, 37 (Supplement 1): S16

**N. Instrument Name:**

FORA GD43 Blood Glucose Meter

**O. System Description:**

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  or No .

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

Yes  or No .

2. Software:

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

Yes  or No .

The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

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 fingertip, palm, forearm, and upper arm. There is not patient identification with this system.

5. Calibration:

Calibration is automatic. The user only needs to verify the code number displayed on the meter matches with the code number on the test strip vial before use.

6. Quality Control:

The FORA Control Solutions are used as quality control checks to make sure that the meter and test strips are working correctly and that the user is performing the test correctly. The labeling provides instructions on when quality control testing should be performed. The control ranges are printed on the test strip vial label.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In the “Performance Characteristics” Section above:**

1) Hematocrit study:

The effect of different hematocrit levels was evaluated using venous whole blood samples with hematocrit levels of 20 - 70% (20, 30, 40, 50, 60 and 70%) spiked with glucose to achieve target concentrations of 40.5, 102.5, 142.5, and 356 mg/dL with 3 lots of test strips. A total of 30 replicates were performed for each combination of strip lot, glucose concentration, and hematocrit level tested. The results demonstrated that the FORA GD43 Blood Glucose Monitoring System produces accurate results over the claimed hematocrit range of 20-70%.

2) Altitude study:

To evaluate the effects of altitude on the FORA GD43 system results, venous blood samples from three donors were altered to 5 glucose concentrations (66, 121, 230, 375 and 560 mg/dL) and tested at various levels of atmospheric pressure and pO<sub>2</sub> levels in a glove box to simulate equivalent altitudes from sea level to 15,000 feet above sea level. The meter results were compared to those obtained with the YSI-2300 analyzer. The results demonstrate acceptable bias to the reference to support the claims in the labeling that altitudes up to 15,000 feet have no significant effect on blood glucose measurements from the FORA GD43 Blood Glucose Monitoring System.

3) Temperature and humidity studies:

The sponsor performed temperature and humidity studies using venous blood samples at target glucose concentrations of 65, 125, and 320 mg/dL to evaluate temperatures ranging from 46-113°F (8-45°C) and relative humidity from 10-90%. Extreme combinations of the claimed temperature and humidity operating conditions were evaluated and meter results compared to a reference method. The results support the claimed range of operating conditions: 46-113°F and 10-90% relative humidity.

4) Sample volume study:

The sponsor performed a sample volume study to support the claimed minimum sample volume requirement for the FORA GD43 system (0.5 µL) using blood samples at three glucose concentrations (42.5, 128, 319 mg/dL). Results support the claimed sample volume of 0.5 µL.

5) Infection Control Studies:

The device is intended for single-patient use. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, MicroKill+ Disinfectant Wipes (EPA registration #598940-10-37549). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 260 cleaning and disinfection cycles (520 wipes). The robustness studies were designed to simulate 5

years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

- 6) Electromagnetic Compatibility (EMC) testing was performed and found to be adequate for the FORA GD43 system.
- 7) FORA Customer Service is available from 7am to 6pm PST, Monday through Friday by calling 1-888-307-8188.

**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.