

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

A. 510(k) Number:

k121706

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative Amperometric, glucose biosensor (glucose oxidase)_

E. Applicant:

FORA Care Inc.

F. Proprietary and Established Names:

FORA V10 No Code Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1345

21 CFR § 862.1660

2. Classification:

Class II, Class I

3. Product code:

NBW, System Test, Blood Glucose. Over The Counter.

CGA, Glucose Oxidase, Glucose

JJX, Single analyte control

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

FORA V10 No Code Blood Glucose Monitoring System, model TD-4244, 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 people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. The meter contains some speaking functions but has not been validated for use for use by visually impaired users. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

This system is intended to be used by a single patient and should not be shared.

FORA V10 test strips are for use with FORA V10 No Code Blood Glucose meter, Model TD-4244, to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, forearm upper arm, calf and thigh.

The FORA control solutions can be used with FORA V10 No Code Blood Glucose Monitoring System, model TD-4244, and the FORA V10 test strips to check that meter and test strips are working together properly.

The alternative site testing in FORA V10 No Code Blood Glucose Monitoring systems can be used only during steady-state blood glucose conditions.

3. Special conditions for use statement(s):

- For in vitro diagnostic use only
- For Over the Counter Use
- Not intended for use on neonates
- Not for diagnosis of or screening for diabetes mellitus
- Not to be used for patients who are dehydrated, hypotensive, in shock, critically ill or in a hyperosmolar state

- Allows alternative site testing from the palm, forearm, upper arm, calf and thigh during steady state blood glucose conditions only
- Single-patient use devices are for single-patients only and should not be shared.
- Results from alternative sites should not be used to calibrate continuous glucose monitors (CGMs) or in insulin dose calculations

4. Special instrument requirements:

FORA V10 No Code Blood Glucose meter (Model TD-4244)

Disposable, single use lancing devices are used with the FORA V10 No Code Blood Glucose Monitoring System

I. Device Description:

The system kit contains a FORA V10 No Code Blood Glucose meter (which is a no code meter), a quick start user guide, owners manual, storage case, warranty card, daily log book and two AAA alkaline batteries. FORA control solutions (Level 1, 2 and 3), FORA V10 Test Strips and disposable sterile lancets, are not included in the system kit but are required and can be purchased separately. RS-232 cable is an accessory to this device and can be purchased separately

FORA V10 users have the option of uploading the stored results into a personal computer (PC) through a cable with the program installed in their PC, Health care System Software, which has been previously cleared under k070941.

J. Substantial Equivalence Information:

1. Predicate device name(s):
FORA V10 Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
k093035
3. Comparison with predicate:

Similarities and Differences		
Item	Candidate Device FORA V10 No Code Blood Glucose Monitoring System, model TD-4244	Predicate Device FORA V10 Blood Glucose Monitoring System (k093035)
Indications For Use/Intended Use	The FORA V10 No Code Blood Glucose Monitoring System, model TD-4244 is intended for use in the quantitative measurement of	Same

Similarities and Differences		
Item	Candidate Device FORA V10 No Code Blood Glucose Monitoring System, model TD-4244	Predicate Device FORA V10 Blood Glucose Monitoring System (k093035)
	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 people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. The meter contains some speaking functions but has not been validated for use by visually impaired users. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.	
Detection Method	Amperometry	Same
Enzyme	Glucose Oxidase	Same
Sample Volume (µL)	0.7 µL	Same
Reaction time	7 second	Same
Measuring Range	20-600 mg/dL	Same
Measurement Unit	mg/dL	Same
Operating Conditions	50°-104°F (10°C-40°C); 10- 85% R.H.	Same
Size (mm)	93.1 (L) x 46.3 (W) x 21.5 (H)	Same
Weight	74.40 g	Same
Power Source	Two 1.5 AAA alkaline batteries	Same
Memory Feature	450 measurements with day and time	Same
Transmission Function	Using RS232 to transmit data to computer	Same
Test Strip Calibration	Coding is not required	Same
Speaking Function	Contains a speaking function	Same
510k Applicant	FORA Care Inc.	TaiDoc Technology Corp.

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

IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995. (General)

IEC 60601-1-2 Medical electrical equipment part 1-2: General requirements for safety- Collateral standard: Electromagnetic compatibility-Requirements and tests.

L. Test Principle:

The system quantitatively measures the concentration of glucose in whole blood with an amperometric glucose biosensor embedded in the meter that measures the volume of electrical signal generated by the reaction of glucose in the blood sample with the metabolizing enzyme system (glucose oxidase) implanted on the test strip. The electrical signal is then translated into the glucose concentration which is displayed on the LCD screen of the meter.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Within-run precision was evaluated using venous whole blood samples spiked to achieve five different glucose concentrations, three reagent strip lots, and 10 FORA V10 No Code blood glucose meters. Each level was evaluated 10 times for a total of 100 tests per each glucose level.

Within-run precision			
Interval 1 (30-50 mg/dL)			
	Lot 1	Lot 2	Lot 3
Mean	38.8	38.8	39.1
SD	1.64	1.52	1.58
CV	4.23%	3.91%	4.06%
Overall mean	38.9		
Overall SD	1.57		
Overall CV	4.04%		
Mean (95% CI)	38.60-39.22		
SD (95% CI)	1.38 – 1.82		

	Interval 2 (51-110 mg/dL)			Interval 3 (111-150 mg/dL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean	78.5	79.4	80.1	117.6	118.3	120.2
SD	2.33	2.22	2.02	2.66	2.97	3.10
CV	2.97%	2.80%	2.53%	2.26%	2.51%	2.58%
Overall mean	79.4			118.8		
Overall SD	2.25			3.12		
Overall CV	2.83%			2.63%		
Mean (95% CI)	78.97-79.85			118.2-119.4		
SD (95% CI)	1.07-2.61			2.74-3.63		

	Interval 4 (151-250 mg/dL)			Interval 5 (251-400 mg/dL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean	201.3	208.6	204.4	303.9	302.7	299.9
SD	6.08	5.59	6.85	8.70	9.00	7.23
CV	3.02%	2.68%	3.35%	2.86%	2.97%	2.41%
Overall mean	204.7			301.9		
Overall SD	6.82			8.34		
Overall CV	3.33%			2.76%		
Mean (95% CI)	203.4-206.1			300.3-303.5		
SD (95% CI)	5.98-7.92			7.32-9.68		

Intermediate precision was evaluated using three glucose control solutions; Level 1 (30-50 mg/dL), Level 2 (96-144 mg/dL), and Level 3 (280-420 mg/dL). The day-to-day precision was evaluated over a ten-day period using three different test strip lots and 10 different FORA V10 No Code blood glucose meters. A summary of the test results is presented below:

Results of intermediate precision

Level 1 control solution (30-50 mg/dL)			
	Lot 1	Lot 2	Lot 3
Mean	40.1	39.6	39.2
SD	1.77	1.65	1.51
Overall mean	39.6		
Overall SD	1.66		
Overall CV	4.19%		
Mean (95% CI)	39.27-39.91		
SD (95% CI)	1.46 – 1.93		

	Level 2 control solution (96-144 mg/dL)			Level 3 control solution (280-420 mg/dL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean	129.6	130.4	128.9	315.3	312.9	309.0
SD	3.62	2.98	3.50	7.59	6.81	7.90
CV	2.80%	2.28%	2.71%	2.41%	2.18%	2.56%
Overall mean	129.6			312.1		
Overall SD	3.42			7.88		
Overall CV	2.64%			2.53%		
Mean (95% CI)	128.9- 130.2			310.5- 313.6		
SD (95% CI)	3.00-3.97			6.92-9.16		

b. Linearity/assay reportable range:

Linearity testing was performed using venous blood samples which were adjusted to 10 different glucose concentrations ranging from 10~20, 21~50, 51~80, 81~120, 121~200, 201~300, 301~400, 401~500, 501~600, and 601~700 mg/dL, as measured by the YSI-2300. Three lots of test strips and 5 FORA V10 No Code glucose meters were used. Each concentration was measured 15 times (with 5 measurements per lot) using the FORA V10 No Code glucose meters. The values obtained using the FORA V10 No Code glucose meter were compared to those obtained by the YSI-2300. The linear regression analysis is as follows:

	Slope	Slope 95% CI	Intercept	Intercept 95% CI	R ²
Lot 1	0.9964	0.9640-1.0064	0.2706	-3.2139-3.7552	0.9988
Lot 2	0.9996	0.9874-1.0117	2.9977	-1.2197-7.2152	0.9983
Lot 3	0.9986	0.9872-1.0086	-1.9360	-5.6567-1.7846	0.9986

The claimed measuring range for this device is 20-600 mg/dL

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

The method comparison was performed using the proposed device and YSI 2300 glucose analyzer. The YSI 2300 is calibrated with NIST (SRM) 917A reference material.

The FORA control solutions solutions are traceable to NIST SRM 917A reference material and YSI-2300. Value assignment was performed with 25 meters, 25 vials of test strips from the same lot and 3 levels of control solutions. The mean, standard deviation and CV are calculated for each new lot of control material.

Test strips stability previously evaluated under *k093035*. The sponsor states that the unopened test strips are stable for 24months when stored at 35.6°F-89.6°F.

Control solutions stability previously evaluated under *k093724*. The sponsor states that the control solutions have an unopened shelf-life of 2 years (24 months) at the recommended storage temperature of 36°-86°F. Open vial stability is 90 days at the recommended storage temperature of 36°-86°F.

d. Detection limit:

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

e. Analytical specificity:

The sponsor indicated that interference testing was performed according to CLSI EP7-A2. Venous blood was obtained from fasting subjects and collected in sodium heparin vacutainer tubes. Two concentrations of glucose were adjusted to 70 mg/dL (low) and 150 mg/dL (high) using the YSI 2300 as a reference analyzer. Glucose samples were then spiked with the potentially interfering compounds equivalent to the highest therapeutic dosage and toxic level (or ten times the highest therapeutic concentrations when toxic levels were unknown). Bias was calculated as the mean percent difference in glucose reading between the test and control concentration groups. All samples tested showed % bias within $\pm 10\%$ between the test and the control groups. The sponsor claims no significant interference ($\leq 10\%$ difference) for the substances and concentrations listed in the table below.

Summary of substances and concentrations without interference

Substance	Therapeutic / Physiologic Concentration Range (or Upper Limit) (mg/dL)*	Highest Concentration Tested without significant interference (mg/dL)*
Acetylsalicylic Acid	2 - 10	50
Acyclovir	0.23 - 0.31	3.1
Allopurinol	0.5	5
Amitriptylline	0.012 - 0.025	0.27
Amoxicillin	0.55 - 1.1	12.5
Ampicillin	0.5	5
Aspirin (Salicylic Acid)	10 - 30	60
Atenolol	0.1 - 0.2	10
Bicarbonate	244 (29 mM)	336 (40 mM)
Bile Acids (Cholic Acid)	0.7	6
Bilirubin (Unconjugated)	0-2	20
Caffeine	0.3 - 1.5	10
Calcium	2.8 mM	5 mM
Captopril	100	0.5 - 3
Chloride	108 mM	140 mM
Cholesterol	300	500
Clonidine	0.0001 - 0.0002	2
Creatinine	1.7	5
Digoxin	0.0001 - 0.00025	0.16
Diphenhydramine	0.01 - 0.1	1
K2EDTA	180	180
K3EDTA	175.5	175.5
Enalapril	0.012 - 0.015	0.15
Erythromycin	0.2 - 2.0	20
Ephedrine Hcl	3	60
Erythromycin	0.2 - 2.0	20
Estrone	0.0011	0.1
Famotidine	0.008 - 0.013	0.13

Fluoxetine	0.08	0.8
Fructose	7.5	1000
Furosemide	0.1 - 0.3	2
Gentisic Acid	0.2 - 0.6	2
Glyburide	0.018 - 0.025	1.07
Heparin (Li)	35-100 U/dL	1700 U/dL
Heparin (Na)	35-100 U/dL	1700 U/dL
Ibuprofen	1 - 7	55
Isomalt	N/A	1000
Lactose	< 0.5	1000
Lactitol	N/A	1000
Lidocaine	0.15 - 0.6	6
Magnesium	1.1 mM	5 mM
Maltitol	N/A	1000
Maltose	N/A	1000
Mannitol	0.0128	1000
Metaproterenol	0.00022 - 0.00130	1.81
Metformin HCl	0.5 - 4	50
Metoprolol	0.005 - 0.027	0.3
Naproxen	3-12	100
Nifedipine	0.017	0.17
Nortriptyline	0.005 - 0.015	0.15
Penicillin	1.2	12
pH value	7.35 - 7.45	6.7 – 9.8
Phenytoin	1 - 2	10
Piroxicam	0.3-0.5	5
Potassium	5.9 mM	10 mM
Sodium	135 - 145 mM	200 mM
Sorbitol	0.044	1000
Sulfamethoxazole	5-12	120
Sulfate	1 mM	5 mM
Terfenadine	0.00015 - 0.00045	0.45
Tetracycline	0.4	4
Theophylline	1.0 - 2.0	25
Tolbutamide	4.32 - 24	64
Total Protein (gamma-Globulin)	6000 - 8000	12000
Triglycerides	30-300	3000

(Lipemic Sample)		
Urea	38	600
Uric acid	2-8	10
Vancomycin	0.025	25
Verapamil	0.014 - 0.045	0.45
Vitamin E	0.5 - 2.0	20
Warfarin	0.1 - 1.0	2
Xylitol	N/A	1000
Xylose	N/A	1000

The test strip insert states the following compounds do not show interference with glucose measurements at the limiting concentrations when using this device:

Substance	Limiting Concentration (mg/dL)	Therapeutic / Physiologic Concentration Range (or Upper Limit) (mg/dL)
Acetaminophen	6.25	0.45 - 3
Ascorbic acid	5	2
Dopamine	1.25	0.03
Levo - Dopa	1.4	0.02 - 0.28
Methyl - Dopa	1.25	0.1 - 0.5
Tolazamide	12.5	1.6
Galactose	250	< 5
Mannose	250	1.15
Glutathione Reduced	23	47 - 100 (intracellular)
Hemoglobin (Hemolysis Method)	100	2.5
Pralidoxime Iodide	5	~ 10 (IV Dose 500 mg)

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

System Accuracy:

The sponsor conducted an accuracy study at three sites within one hospital. Trained professionals obtained 210 samples from diabetic and non-diabetic outpatient participants. The range of glucose values of the participants tested was 35 – 526 mg/dL. Samples that were <50 mg/dL and >400 mg/dL were contrived samples and samples between 50 and 400 mg/dL were natural capillary samples from the fingertip. A total of 13 contrived samples were used in the study.

Accuracy results for glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ± 15 mg/dL
18/35 (51.4%)	34/35 (97.1%)	35/35 (100%)

System accuracy results for glucose concentrations ≥ 75 mg/dL

Within ±5 %	Within ±10 %	Within ± 15 %	Within ± 20%
72/175 (41.1%)	133/175 (76.0%)	168/175 (96.0%)	175/175 (100%)

Regression Analysis vs. YSI

	N	Slope and y-intercept	R ²
FORA V10 No Code meter vs. YSI	210	Y=0.9608x-1.5578	0.9804

b. Matrix comparison:

System Accuracy-(Alternative Sites) HCP vs YSI

The sponsor conducted an accuracy study at the claimed alternative sites (palm, forearm, upper arm, calf and thigh) Trained professionals obtained 150 samples from diabetic and non-diabetic participants. The glucose concentrations of the alternative site samples tested by YSI were 56-451 mg/dl. Samples that were >400 mg/dL were contrived samples and samples between 50 and 400 mg/dL were natural samples. There were 3 contrived samples used in this study.

Results for glucose concentrations <75 mg/dL

	Within ±5 mg/dL	Within ± 10 mg/dL	Within ±15 mg/dL
Palm	77/22 (77%)	21/22 (96%)	22/22 (100%)
Forearm	13/22 (59%)	21/22 (96%)	22/22 (100%)
Upper Arm	10/20 50%	19/20 (95%)	20/20 100%
Calf	11/20 55%	19/20 (95%)	20/20 (100%)
Thigh	9/20 45%	19/20 (95%)	20/20 (100%)

Results for glucose concentrations ≥ 75 mg/dL

	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Palm	45/128 (35%)	82/128 (64%)	123/128 (96%)	128/128 (100%)
Forearm	42/128 (33%)	86/128 (67%)	122/128 (95%)	128/128 (100%)
Upper Arm	39/130 (30%)	89/130 (69%)	125/130 (96%)	130/130 (100%)
Calf	41/130 (32%)	104/130 (80%)	126/130 (97%)	130/130 (100%)
Thigh	45/130 (35%)	99/130 (76%)	125/130 (96%)	130/130 (100%)

Palm	$Y=0.9592x-1.8092, R^2=0.9793$
Forearm	$Y=0.9618x-3.7831, R^2=0.9823$
Upper Arm	$Y=0.9878x-7.6443, R^2=0.9861$
Calf	$Y=0.9846x-5.8126, R^2=0.9833$
Thigh	$Y=0.9804x-6.0559, R^2=0.9852$

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):*

A user performance study was performed to demonstrate that untrained lay users can correctly perform a glucose test using the FORA V10 No Code Blood Glucose Monitoring System and obtain accurate results. There were 210 male and female study participants of varying demographics. Each participant was asked to perform a self test using only the provided labeling written in the English language. Following testing by the lay-user, a venous blood specimen from each subject was also obtained by a healthcare professional (HCP) and tested on the YSI-2300 reference analyzer. The meter results compared to YSI results in ISO 15197 format are summarized in the tables below.

Results for glucose concentration <75 mg/dL

Operator	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Lay User	18/36 (50.0%)	32/36 (88.9%)	36/36 (100%)

Results for glucose concentration ≥ 75 mg/dL

Operator	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Lay User	62/174 (35.6%)	136/174 (78.2%)	169/174 (97.1%)	174/174 (100%)

Regression analysis between the lay users and HCP collected fingerstick results with the YSI method:

Comparison	n	Slope	y-intercept	R
Lay User vs. YSI	210	1.059	-7.848	0.9831

Alternative testing sites: palm, forearm, upper arm, calf and thigh were performed using 150 participants, 6 FORA V10 No Code Blood Glucose meters and 3 lots of FORA V10 test strips. Alternative site testing was performed by the lay user and HCP. Glucose levels were collected during times of steady state conditions. The range of glucose values for these samples was 53~422 mg/dL (by YSI). The linear regressions were as follows:

Results for glucose concentrations <75 mg/dL

	Within ±5 mg/dL	Within ± 10 mg/dL	Within ±15 mg/dL
Palm	15/22 (68.2%)	21/22 (96.0%)	22/22 (100.0%)
Forearm	13/22 (59.0%)	21/22 (96.0%)	22/22 (100.0%)
Upper Arm	10/20 (50.0%)	19/20 (95.0%)	20/20 (100.0%)
Calf	11/20 (55.0%)	19/20 (95.0%)	20/20 (100.0%)
Thigh	9/20 (45.0%)	19/20 (95.0%)	20/20 (100.0%)

Results for glucose concentrations ≥ 75 mg/dL

	Within ±5 %	Within ± 10%	Within ±15 %	Within ± 20%
Palm	45/128 (35.0%)	82/128 (64.0%)	123/128 (96.0%)	128/128 (100.0%)
Forearm	42/128 (33.0%)	86/128 (67.0%)	122/128 (95.0%)	128/128 (100.0%)
Upper Arm	39/130 (30.0%)	89/130 (69.0%)	125/130 (96.0%)	130/130 (100.0%)
Calf	41/130 (32.0%)	104/130 (80.0%)	126/130 (97.0%)	130/130 (100.0%)
Thigh	45/130 (35.0%)	99/130 (76.0%)	125/130 (96.0%)	130/130 (100.0%)

Summary of regression analysis

Palm	$y=0.9743x-3.6757$, $R^2=0.9807$
Forearm	$y=0.9605x-4.0773$, $R^2=0.9839$
Upper Arm	$y=0.9808x-6.3254$, $R^2=0.9859$
Calf	$y=0.9773x-5.2678$, $R^2=0.9821$
Thigh	$y=0.9853x-6.1778$, $R^2=0.9850$

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Time of day	Normal plasma glucose range for people without diabetes
Fasting and before meals	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. Standards of Medical Care in Diabetes-2011, Diabetes Care 2011;34 Suppl 1):S11-S61

N. Instrument Name:

FORA V10 No Code Blood Glucose Meter (Model TD-4244)

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___ 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 _____

The applicant has provided documentation that indicated 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, the palm, the forearm, the upper arm, the calf, and thigh. The whole blood is applied directly to the test strip so therefore no special handling or storage is needed.

5. Calibration:

This is a no code meter. The FORA V10 test strips contain the calibration code. There is no coding by the user.

6. Quality Control:

The sponsor states that the system can be used only with FORA control solutions (cleared under k093724). Recommendations on when to test the control materials are provided in the labeling. An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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 with one lot of test strips and six FORA V10 No Code Blood Glucose meters. Blood samples at six concentrations (20-30, 50-80, 100-150, 201-250, 351-400, 551-600 mg/dL) were analyzed. The glucose samples were prepared from venous blood at five different hematocrit levels 20, 30, 40, 50, and 60%. Glucose results for each concentration and hematocrit level were compared to samples tested on the YSI reference method. The data supports the sponsor’s claim that hematocrit in the range of 20-60% does not significantly interfere (more than $\pm 15\%$) with glucose measurements using the FORA V10 No Code Glucose Monitoring System.

2. Altitude:

An altitude study was conducted to evaluate the effect of altitude up to 10,742 feet on performance of the FORA V10 No Code Blood Glucose Monitoring System using a glove box system which simulates 4 elevations from sea level to 15,000 feet (4500 meters), atmospheric pressure from 429 - 760 mmHg, and P02 from 32-102 mmHg. Venous whole blood samples at five glucose concentrations ranging from 50-600mg/dL were tested at four altitudes using three FORA V10 Blood Glucose meters and one lot of test strips. Each sample was also evaluated by the YSI method. At altitudes up to 15,000 feet, test results were within $\pm 10\%$ of the YSI values.

3. Test System operating conditions:

Studies were performed using four FORA V10 No Code Blood Glucose meters, three lots of test strips, and three venous whole blood samples with glucose concentrations of ~65, ~125 and ~320 mg/dL. Testing was performed at four combined temperature and humidity conditions (50°F/10% RH, 50°F/85%RH, 50°F/10%RH and 40°C/85%RH) as well as the claimed conditions 50-104°C (10-40°C) and at a relative humidity from 10-85% and results compared to the reference YSI. There were no significant differences in glucose concentrations across the temperature and humidity ranges tested. Results demonstrated that the test system can be used at temperatures from 50-104°F (10-40°C) and at a relative humidity from 10-85%.

4. User performance study:

During the lay user study described above in Section M.3.c, the participants were asked to complete a questionnaire to evaluate the ease of use of the device and the clarity of the English language labeling. Overall the users indicated that they could successfully perform the test and that the user manual was written clearly.

5. Readability Assessment:

The readability of the labeling (user guides, test strip package insert and control solution package insert) using a Flesch-Kincaid analysis were found to be written at the 8th grade level.

6. EMC Testing:

The sponsor provided the appropriate documentation certifying that electromagnetic testing (EMC) had been performed and the FORA V10 No Code Blood Glucose Meter was found compliant.

7. Speaking Function:

The sponsor has provided the validation studies for the Speaking Functions of the FORA V10 No Code Blood Glucose Monitoring System. The Speaking Function Validation test was deemed to be acceptable

8. Infection Control:

The device is intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing lab demonstrating complete inactivation of hepatitis B Virus (HBV) with the chosen disinfectant, Micro-Kill Plus™ disposable wipes (EPA Reg. No: 59894-10-37549). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 5,000 cleaning and disinfection cycles, using Micro-Kill Plus™ disposable wipes, to simulate 5 years of use by lay users. Labeling has been reviewed for adequate instructions in validated cleaning and disinfection procedures.

9. Software validation:

Software validation and verification has been reviewed and the information provided was deemed to be adequate..

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.