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

A. 510(k) Number:

K173505

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose from the fingertip

D. Type of Test:

Quantitative amperometric assay (Glucose Dehydrogenase FAD)

E. Applicant:

ForaCare Inc.

F. Proprietary and Established Names:

FORA GTel 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

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indication(s) for use below

2. Indication(s) for use:

   FORA GTel Blood Glucose Monitoring System

   The FORA GTel Blood Glucose Monitoring System consists of the FORA GTel Test Strip and the FORA GTel Blood Glucose meter.

   The FORA GTel Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood drawn from the finger. It is intended for in vitro diagnostic use by 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. It is intended to be used by a single person and should not be shared.

3. Special conditions for use statement(s):

   - For *in vitro* diagnostic use (for use outside of the body only).
   - For single-patient use only.
   - This system should not be used for the diagnosis of, or screening for diabetes.
   - This system is not for use on patients with abnormally low blood pressure.
   - Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hypoglycemic hyperosmolar state, with or without ketosis.
   - This system should not be used on neonates or critically ill patients.
   - This system should not be used on patients with impaired peripheral circulation, severe dehydration as a result of diabetic ketoacidosis or severe hyperglycemia, hyperosmolar non-ketotic coma or shock.
   - Altitudes above 10,742 feet may cause inaccurate results.
   - This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

4. Special instrument requirements:

   FORA GTel Blood Glucose Meter

I. Device Description:

The FORA GTel Blood Glucose Monitoring System consists of the FORA GTel Blood Glucose Meter, Owner's Manual, Protective Wallet, Quick Start User Guide, Daily Log Book, Warranty Card and 1 x Li-ion rechargeable batteries. The FORA GTel Test Strips were previously cleared under k143467 as the FORA GD34 Test Strips and are for use with the FORA GTel Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood from the fingertip. The FORA GTel Test Strips need to be purchased separately. The control solutions to be used with the FORA GTel System are the FORA Control Solutions, Level 1, Level 2, and Level 3 and need to be purchased separately. The FORA GTel Blood Glucose Monitoring System includes a speaking feature that provides audible test results for diabetic users.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   FORA GD43 Blood Glucose Monitoring System

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

   k143467

3. Comparison with predicate:

Similarities		
Characteristic	**Candidate Device** FORA GTel Blood Glucose Monitoring System	**Predicate Device** FORA GD43 Blood Glucose Monitoring System (k143467)
Intended Use	Intended for the quantitative measurement of glucose as an aid in monitoring the effectiveness of a diabetes control program.	Same
Methodology	Glucose Dehydrogenase	Same
Patient-Use	Single-patient use	Same
Intended Use Population	Over-the-counter	Same
Sample Type	Capillary whole blood samples drawn from fingertips	Same
Measurement range	20-600 mg/dL	Same

Differences		
Characteristic	**Candidate Device** FORA GTel Blood Glucose Monitoring System	**Predicate Device** FORA GD43 Blood Glucose Monitoring System (k143467)
Alternative Sites	No	Yes, forearm, upper arm, or palm
Talking function	Yes	No
Data transmission	3G	RS-232 4 Poles

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

CLSI EP05-A2 – Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.

CLSI EP06-A – Evaluation of Linearity of Quantitative Measurement Methods: A Statistical Approach; Approved Guideline (2003)

CLSI EP07-A2 – Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition (2005)

IEC/EN 61010-1, Safety requirements for electrical equipment measurement, control, and laboratory use – Part 1: General requirements, Ed 3.0 (2010)

IEC 62304, Medical Device Software -Software Life Cycle Processes, Ed 1.1 (2015)

L. Test Principle:

The system measures the amount of sugar (glucose) in whole blood. The glucose testing is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current, calculates the blood glucose level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within-run (Repeatability)

Within-run precision studies were performed using venous whole blood samples of 5 glucose levels (30-50, 51-110, 111-150, 151-250, 251-400 mg/dL). Samples were

tested ten times with each of three lots of test strips with 10 meters for a total of 300 tests per glucose concentration and a grand total of 1500 tests. Results are summarized below:

Glucose Level (mg/dL)	Lot	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	1	48.1	1.3	2.7
	2	47.9	1.3	2.8
	3	48.2	1.3	2.7
51-110	1	101.3	1.7	1.7
	2	104.8	1.9	1.8
	3	102.0	1.9	1.8
111-150	1	147.2	2.6	1.8
	2	151.5	2.0	1.3
	3	148.2	2.4	1.6
151-250	1	247.7	3.9	1.6
	2	250.5	4.0	1.6
	3	244.8	4.3	1.8
251-400	1	398.4	6.5	1.6
	2	399.2	6.4	1.6
	3	389.6	6.4	1.7

Intermediate Precision

Intermediate (between run) precision was evaluated using five levels of glucose control solutions, 3 test strip lots, and 10 meters. Each control solution level was measured once a day for 10 days with each meter and test strip lot, for a total of 100 replicates per control solution level per test strip lot for a total of 300 replicate for each glucose control level. Results are summarized below:

Control Solution Level (mg/dL)	Lot	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	1	49.8	2.02	4.1
	2	49.0	2.09	4.3
	3	48.8	1.98	4.1
51-110	1	96.0	2.28	2.4
	2	95.8	1.94	2.0
	3	96.0	1.80	1.9
111-150	1	135.8	2.07	1.5
	2	135.2	2.14	1.6
	3	134.8	2.32	1.7
151-250	1	225.8	2.77	1.2
	2	225.2	2.74	1.2
	3	224.6	2.39	1.1
251-400	1	315.4	3.70	1.2

Control Solution Level (mg/dL)	Lot	Mean (mg/dL)	SD (mg/dL)	CV (%)
	2	314.3	3.84	1.2
	3	316.5	4.24	1.3

b. Linearity/assay reportable range:

Linearity testing was performed using venous whole blood samples spiked to 11 target analyte levels (10, 26, 65, 99, 148, 160, 249, 354, 439, 552, and 621 mg/dL). Each sample was measured in replicates of 15 with 3 test strip lots and 5 meters and the values compared to a laboratory-based comparator method (YSI 2300 glucose analyzer).

The evaluation yielded the following regression equations for the three lots based on all samples:

Lot 1 $y = 1.0080x – 0.9462$, $R^2 = 0.9993$

Lot 2 $y = 1.0085x – 0.663$, $R^2 = 0.9992$

Lot 3 $y = 1.0064x – 0.6586$, $R^2 = 0.9986$

The results of the study support the sponsor's claimed glucose measuring range of 20-600 mg/dL. The meter displays "Low" with glucose values below 20 mg/dL, and "High" with glucose values over 600 mg/dL. The "Low" and "High" functions were validated and demonstrated to function as intended.

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

The FORA GTel Blood Glucose Monitoring System is traceable to the NIST SRM 917c glucose reference material.

Test Strip Stability

Test strip stability has been evaluated through accelerated and real-time open vial and closed vial studies. Protocols and acceptance criteria were reviewed and found to be acceptable. The manufacturer labeled claims for shelf life stability and open vial stability of 24 months when stored at 35.6- 86°F (2-30˚C) and 10% to 90% relative humidity.

d. Detection limit:

The reportable range for the FORA GTel Blood Glucose Monitoring System is 20-600 mg/dL. See the linearity studies (section M.1.b.) above.

e. *Analytical specificity:*

Potential interfering substances were evaluated at three glucose concentration intervals (61, 119, and 264 mg/dL) by analyzing 39 potentially interfering exogenous and endogenous substances. Glucose values measured with the FORA GTel Blood Glucose Monitoring System in venous samples were spiked with a potentially interfering substance and results compared with values measured in control samples (without potentially interfering substance) on the FORA GTel Blood Glucose Monitoring System. The sponsor defined significant interference as bias greater than ±10% (versus control condition). The compounds at the concentrations listed below were the highest concentrations tested that did not demonstrate significant interference:

Potential Interferent	**Highest concentration tested at which no significant interference is observed (mg/dL)**
Acetaminophen	20
Ascorbic Acid	5
Bilirubin (Conjugated)	50
Bilirubin (Unconjugated)	40
Cholesterol	500
Creatinine	30
Dopamine	2.5
Galactose	1000
Gentisic Acid	5
Glutathione Reduced	30
Hemoglobin	14700
Heparin (Na)	790 U/dL
Ibuprofen	55
Icodextrin	2000
Isomalt	1000
Lactitol	1000
L-DOPA	2.1
Maltitol	1000
Maltose	1000
Mannitol	5000
Mannose	200
Methyldopa	1.25
Salicylate	60
Sodium	460
Sorbitol	1000

Potential Interferent	Highest concentration tested at which no significant interference is observed (mg/dL)
Tolbutamide	100
Xylitol	1000

The sponsor has included the following in the labeling:

- Acetaminophen in your blood ≥ 20 mg/dL might affect the reliability of your blood glucose results. If you are taking Tylenol, your glucose results may not be reliable. If you are unsure, then ask your doctor.
- If you have a disease or condition that elevates your blood uric acid level (>10 mg/dL), such as gout, your blood glucose results may not be reliable. If you are unsure, then ask your healthcare professional.
- If you are taking high doses of Tolazamide (> 20 mg/dL in your blood), then you should know that this drug might affect the reliability of your blood glucose results. If you are unsure, then ask your healthcare professional
- Xylose: Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can give falsely elevated results.
- Pralidoxime iodide level to > 5 mg/dL may affect the glucose results. If you are unsure, then ask your doctor.

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable. See User Performance Studies below (section M.3.d) for demonstration of system accuracy in the hands of the intended user.

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 GTel Blood Glucose Monitoring System in the hands of lay users, the sponsor performed a study with 350 lay user participants who collected and tested their own fingertip capillary blood samples. Participants were from two private general medicine clinics and one outpatient research center specializing in diabetes and endocrinology. The glucose concentrations in the samples ranged from 52-390 mg/dL as measured by the laboratory reference method (YSI 2300). Results were analyzed by comparing blood glucose results obtained from the FORA GTel Blood meter by the lay user against the YSI 2300 laboratory reference value obtained by healthcare professionals. Results are summarized in the tables below:

Within ± 5 %	**Within ± 10 %**	**Within ± 15 %**	**Within ± 20 %**
249/350 (71.1%)	332/350 (94.9%)	349/350 (99.7%)	350/350 (100%)

$y = 1.0101 x + 2.1204$, $R^2 = 0.9906$

During the lay user study participants were asked to complete a questionnaire to evaluate the use of the device and the clarity of user manual. Overall the users indicated that they could successfully conduct the test.

4. Clinical cut-off**:**

Not Applicable

5. Expected values/Reference range:
Normal plasma glucose range for people without diabetes:
   - Fasting and before meal: < 100 mg/dL (5.6 mmol/L)
   - 2 hours after meals: < 140 mg/dL (7.8 mmol/L)

American Diabetes Association. Standards of Medical Care In Diabetes – 2018 Jan; 41 (Supplement 1): S1-S2

N. Instrument Name:

FORA GTel Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

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 __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:

The device is intended to be used with capillary whole blood from the fingertip. The whole blood is applied directly to the test strip, so there are no special sample storage or handling considerations.

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 properly. The labeling provides instructions on when quality control testing is performed. Control solutions must be purchased separately from the system.

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

1. Sample Volume Study

The sponsor performed a study to evaluate the minimal sample volume requirement for the FORA GTel Blood Glucose Monitoring Systems using blood samples at volumes of 0.30 µL, 0.40 µL, 0.50 µL, 0.60 µL, 0.70 µL, and 0.80 µL. Five blood glucose meters were used in this assessment and three lots of test strips to evaluate venous blood altered to glucose concentrations of60, 112 mg/dL, and 222 mg/dL. This testing supported the claimed minimum sample volume of 0.50 µL for this device and that the sample detection feature functioned as intended when the sample volume was <0.50 µL.

2. Altitude Study

To evaluate the effects of altitude, one test strip lot was tested with 4 meters using venous blood altered to glucose concentrations of 55, 106, 158, 257, 388, 476, and 592 mg/dL. The samples were tested at various levels of pO2 levels in a glove box to simulate equivalent altitudes from sea level to 15,000 feet above sea level. Results obtained were compared with those obtained with a laboratory-based comparator method (YSI 2300 analyzer). The results demonstrate acceptable bias relative to the comparator method to support the claim in the labeling that the meter can be used at altitudes up to 10,742 ft.

3. Hematocrit Study

The effect of different hematocrit levels was evaluated using venous whole blood. FORA GTel Blood Glucose Monitoring System was tested with venous blood altered to glucose concentration of 46.5, 102.5, 142.5, 233, and 372 mg/dL and thirteen hematocrit levels (10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65 and 70%). Each sample was measured on ten meters for each of three test strip lots and in replicates of four for each of the three test strips with an established a laboratory-based comparator method (YSI 2300). Results of samples at each hematocrit level were compared to samples measured with an established a laboratory-based comparator method (YSI 2300) and support the claimed hematocrit range of 20-60%.

4. Test System Operating Conditions

Four FORA GTel meters were used to test venous whole blood samples with three lots of blood glucose test strips. Five test conditions were used in this study: 6 °C/ 10% RH, 6 °C/ 90% RH, 25 °C/ 60% RH, 47 °C/ 10% RH, 47 °C/ 90% RH. The protocol and acceptance criteria for this test were found to be acceptable. The results supported the sponsor's claimed operating conditions of 46.4 °F-113 °F (8 °C– 45 °C) and a relative humidity range of 10% to 90%.

5. Readability Assessment

The readability of the labeling (user manual and test strip insert) using Flesch-Kincaid's analysis were found to be written not higher than 8th grade level.

6. EMC Testing

The sponsor provided documentation certifying that acceptable electromagnetic testing (EMC) has been performed and the System was found to be compliant.

7. Infection Control and Robustness Studies

The FORA GTel is intended for a single-patient only. 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 designed to simulate 5 years of single-patient use. The subject device labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

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.