



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

I Background Information:

A 510(k) Number

K201037

B Applicant

Taidoc Technology Corporation

C Proprietary and Established Names

FORA ADVANCED GD40 Glucose, B-Ketone and Cholesterol Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry
JIN	Class I, meets the limitations of exemption 21 CFR 862.9(c)(5)	21 CFR 862.1435 - Ketones (nonquantitative) test system	CH - Clinical Chemistry
CHH	Class I, meets the limitations of exemption 21 CFR 862.9(c)(4)	21 CFR 862.1175 - Cholesterol (total) test system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Addition of a cholesterol assay to a cleared device for glucose and ketones

B Measurand:

Glucose, β -Ketone, and Total Cholesterol

C Type of Test:

Quantitative Amperometric assay (Glucose, β -Ketone, and Total Cholesterol)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The FORA ADVANCED GD40 Glucose, β -Ketone and Cholesterol Monitoring System consists of the FORA ADVANCED GD40 meter, the FORA ADVANCED GD40 Blood Glucose strips, the FORA ADVANCED GD40 β -Ketone strips, and the FORA ADVANCED GD40 Total Cholesterol strips.

The FORA ADVANCED GD40 Glucose, β -Ketone and Cholesterol Monitoring System is intended for the quantitative measurement of glucose, beta-hydroxybutyrate (β -ketone), and cholesterol in fresh capillary whole blood from the finger. This system is intended for single-patient home use and should not be shared. This device is intended for use by patients with diabetes. It is only for use outside the body (in vitro diagnostic use).

Glucose and β -ketone measurements are used as an aid to monitor the effectiveness of a diabetes control program. Glucose measurements should not be used for the diagnosis of or screening for diabetes.

Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Cholesterol should be measured at the frequency recommended by your healthcare provider.

C Special Conditions for Use Statement(s):

- OTC – Over The Counter
- For in vitro diagnostic use (for use outside the body only)
- For single-patient use only
- The system should not be used for the diagnosis of or screening for diabetes.
- This system is not for use in patients with abnormally low blood pressure or those who are in shock.
- This system is not for use in patients in hyperglycemic-hyperosmolar state, with or without ketosis.
- This system should not be used on 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
- The test strips are NOT for use with neonates.
- Altitude effects: This device should not be used at an altitude higher than 10,742 feet (3274 meters) above sea level
- 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
- FOR CHOLESTEROL ONLY (This limitation does not apply to testing glucose or ketones levels.)
 - Users with very high triglyceride levels (>700 mg/dL) should not use this device to test their cholesterol level.
 - All other users should only check their cholesterol levels first thing in the morning before they have eaten to avoid possible incorrect cholesterol results due to very high triglyceride levels. Triglyceride levels above 700 mg/dL may lead to incorrect cholesterol results. Triglyceride levels may be higher after a meal. If you have questions about your triglyceride level, talk to your healthcare professional.

D Special Instrument Requirements:

Fora ADVANCED GD40 Meter

IV Device/System Characteristics:

A Device Description:

The FORA ADVANCED GD40 Glucose, β -Ketone and Cholesterol Monitoring System consists of the FORA ADVANCED GD40 Meter, the FORA ADVANCED GD40 Blood Glucose strips, the FORA ADVANCED GD40 β -Ketone strips, the FORA ADVANCED GD40 Total Cholesterol strips, and control solutions (3 levels for glucose, 2 levels for ketone, and 2 levels for cholesterol). The test strips and controls are required but not included with the system kit and must be purchased separately. A lancing device and sterile lancets are also required but not included with the system kit and must be purchased separately.

The FORA ADVANCED GD40 glucose and β -Ketone strips, and the FORA glucose and β -ketone control solutions were previously cleared in k161738. The meter was also previously cleared (k161738) as the FORA ADVANCED GD-40 Blood Glucose and β -Ketone meter (now the FORA ADVANCED GD-40 meter). The FORA ADVANCED GD40 Total Cholesterol strips and FORA cholesterol control solutions are new.

B Principle of Operation:

Glucose measurement is based on electrochemical biosensor technology using the enzyme, glucose dehydrogenase, to catalyze the formation of gluconolactone from the oxidation of glucose whereby two electrons are produced. The electrical current resulting from this enzymatic reaction is measured and correlated to glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample. The test strip is calibrated to display the equivalent of plasma glucose values to allow comparison of results with laboratory methods.

Using the same technology, β -hydroxybutyrate (β -ketone) is converted by β -hydroxybutyrate dehydrogenase and the magnitude of electrical current resulting from this enzymatic reaction is proportional to the amount of β -hydroxybutyrate present in the sample.

Cholesterol esters in serum are completely hydrolyzed by cholesterol esterase to free cholesterol and free fatty acids, whereby liberated cholesterol, plus any endogenous free cholesterol, are oxidized by cholesterol oxidase and the magnitude of electrical current resulting from this enzymatic reaction is proportional to the amount of cholesterol present in the sample.

Instrument Description Information:

1. Instrument Name:

FORA ADVANCED GD40 Meter

2. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

3. Specimen Sampling and Handling:

The device is intended to be used with capillary whole blood from the finger. The whole blood sample is applied directly to the test strip by capillary action.

4. Calibration:

A code strip is provided, and the user is instructed to calibrate every time a new vial of total cholesterol test strips is begun. Coding is similar for β -ketone. The code strips contain lot specific test strip information such as the calibration curve and the test strip lot number. Users are instructed to ensure that the code number on the meter display, code strip, and test strip vial are the same before proceeding with testing. Glucose measurements do not require coding.

5. Quality Control:

The sponsor provides 3 levels of FORA Glucose Control Solutions, 2 levels of β -Ketone Control Solutions, and 2 levels of Total Cholesterol Control Solutions. The controls are used

to check that the that the meter, code strips (for cholesterol and β -ketones) and test strips are working together properly and that the test is performing correctly. Control solutions for glucose and β -ketones are recognized automatically by the meter while the user must mark cholesterol control solution as such. Users are instructed to run controls:

- When using the meter for the first time.
- At least once a week to routinely check the meter and test strips.
- With a new vial of test strips.
- If the user suspects the meter or test strips are not working properly.
- If the test results are not consistent with how the user feels, or if the user thinks the results are not accurate.
- To practice the testing process
- If the user has dropped the meter or suspects they may have damaged it.

The acceptable range for the control solutions is printed on the side of the test strip vial.

V Substantial Equivalence Information:

A Predicate Device Name(s):

FORA ADVANCED GD-40 Blood Glucose and β -Ketone Monitoring System
Mission Cholesterol Monitoring System

B Predicate 510(k) Number(s):

k161738
k163406

C Comparison with Predicate(s):

Device & Predicate Device(s):	K201037 (candidate)	K161738
Device Trade Name	FORA ADVANCED GD40 Glucose, β -Ketone and Cholesterol Monitoring System	FORA ADVANCED GD-40 Blood Glucose and β -Ketone Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications for Use	For the quantitative measurement of glucose and β -ketone (beta hydroxybutyrate) in fresh capillary whole blood from the finger.	Same
Intended Use Environment	Over-the-counter	Same
Test Range for glucose	20 – 600 mg/dL	Same
Sample volume for glucose	0.9 μ L	Same

Device & Predicate Device(s):	K201037 (candidate)	K161738
Test time for glucose	5 seconds	Same
Test Range for β -ketone	0.1 – 8.0 mmol/L	Same
Sample volume for β -ketone	0.1 μ L	Same
Test time for β -ketone	10 sec	Same
Calibration for β -ketone	Calibration strip	Same
Sample type	Fingertip Capillary whole blood	Same

General Device Characteristic Differences		
Analytes	Glucose, β -ketone (beta hydroxybutyrate), and cholesterol	glucose and β -ketone (beta hydroxybutyrate)

Device & Predicate Device(s):	K201037 (candidate)	K163406
Device Trade Name	FORA ADVANCED GD40 Glucose, β -Ketone and Cholesterol Monitoring System	Mission Cholesterol Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications for Use	For the quantitative measurement of total cholesterol in capillary whole blood from the fingertip.	Same
Sample Type	Fingertip capillary whole blood	Same
Test Range	100 – 400 mg/dL	Same
Calibration	Test strip	Same
Operating principle	Enzymatic	Same
Calibration	Coded strip	Same

General Device Characteristic Differences		
Intended Users	Diabetics	All users
Intended Use Setting	Over-the-counter home-use	Over-the-counter home-use and prescription use
Test time	60 seconds	< 2 minutes
Analytes	Glucose, β -ketone (beta hydroxybutyrate), and total cholesterol	Total cholesterol, HDL cholesterol, and triglycerides

VI Standards/Guidance Documents Referenced:

- IEC 60601-1-2:2014 (Fourth Edition) Medical electrical equipment - part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- Clinical and Laboratory Standards Institute (CLSI) EP5-A3, Ed.3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline
- CLSI EP7, Ed.3: Interference Testing in Clinical Chemistry
- CLSI EP17-A2, Ed.2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures

VII Performance Characteristics (if/when applicable):

The device in the current submission k201037 is identical to the predicate device for the glucose and β -ketone functions cleared under k161738. The current submission was for the addition of the cholesterol strips only.

A Analytical Performance:

1. Precision/Reproducibility:

Intermediate Precision Study 1:

Three (3) lots of test strips were evaluated using two (2) levels of total cholesterol control solutions (normal and high levels) and ten (10) meters. Ten (10) measurements were obtained per level of control solution on ten (10) days (100 measurements per level per lot). The study was conducted by one (1) operator. The data was analyzed by ANOVA and the results are summarized in the table below.

Control Solution Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1 (180 mg/dL)	1	100	180.7	4.00	2.21
	2	100	180.2	4.27	2.37
	3	100	180.0	4.07	2.26
	All lots combined	300	180.3	4.11	2.28
Level 2 (270 mg/dL)	1	100	269.7	6.11	2.27
	2	100	269.8	6.20	2.30
	3	100	269.2	6.40	2.38
	All lots combined	300	269.5	6.22	2.31

Intermediate Precision Study 2:

Three (3) different, native, venous blood samples with varying levels of cholesterol concentrations were used. Ten (10) measurements per sample on each of ten (10) instruments

were obtained using three (3) lots. The study was conducted by five (5) operators on one (1) day. The data was analyzed by ANOVA and the results are summarized in the table below.

	Interval 1 (180 mg/dL)			Interval 2 (240 mg/dL)			Interval 3 (350 mg/dL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean	171.8	172.2	172.4	245.9	246.2	244.8	330.9	331.9	333.6
SD	3.79	3.70	3.48	5.38	5.48	5.31	7.61	7.64	7.78
CV (%)	2.20	2.15	2.02	2.19	2.23	2.17	2.30	2.30	2.33

Multi-site Precision:

A multi-site precision study was conducted at three (3) sites using two (2) levels of native venous whole blood samples (P2 and P3) and two (2) levels of quality controls (Q2 “normal range” and Q3 “high range”). Three (3) operators conducted testing using two (2) meters per site on five (5) days. Five (5) replicates per sample were tested on one (1) run per day. All sites used the same three (3) reagent and calibrator lots. The data was analyzed by ANOVA and the results are summarized below. The venous whole blood samples (P2 and P3) were prepared fresh for each testing day.

			Within-Laboratory		Reproducibility		Between-site	
Sample	N	Mean	SD	CV %	SD	CV %	SD	CV %
P2	225	179.2	2.55	1.42	2.69	1.50	2.40	1.34
P3	225	240.6	3.02	1.26	3.49	1.45	4.29	1.79
Q2	225	181.8	3.04	1.67	3.89	2.14	4.32	2.37
Q3	225	271.6	5.88	2.16	8.06	2.97	5.91	2.17

2. Linearity:

The sponsor provided a linearity study using three (3) lots of test strips, five (5) meters, one (1) high level (>400 mg/dL), and one (1) low level (<100 mg/dL) native venous blood samples. The high and low samples were used to prepare nine (9) samples ranging from 96 - 405 mg/dL with a known relationship to each other. For each level, the mean of five (5) measurements was compared to the expected value.

The maximum deviation from linearity that was observed within the claimed measuring interval for all three lots was 2.2%.

The results of the linearity study support the claimed measuring range of 100-400 mg/dL for total cholesterol.

3. Analytical Specificity/Interference:

An endogenous and exogenous interference study was performed in accordance with CLSI EP7, Ed.3: Interference Testing in Clinical Chemistry. The study used four (4) meters and test strips from one (1) lot. Two (2) venous whole blood samples at cholesterol concentrations of approximately 180 mg/dL and 240 mg/dL from healthy subjects were used. Samples with native

analyte were supplemented with potentially interfering compounds at levels listed in the table below.

Samples were tested in singlicate using four candidate meters. The four meter measurements were averaged and the percent bias between control and test samples was calculated. Non-interference was defined as a difference of $\leq 10\%$ from the control sample. If the percent bias was greater than $\pm 10\%$, a dose response test was performed to determine the highest concentration of interfering substance that does not interfere with assay performance. The percent bias between control and test samples was calculated as follows:

$$\text{Bias}\% = \{[\text{Mean}(\text{test}) - \text{Mean}(\text{control})] / \text{Mean}(\text{control})\} \times 100\%$$

Results are summarized in the table below:

Potential Interferent	Highest concentration tested that did not cause interference
Acetaminophen (Paracetamol)	15 mg/dL
Acetylsalicylic Acid	65 mg/dL
Ampicillin	5.3 mg/dL
Ascorbic acid	7.5 mg/dL
Atorvastatin	0.06 mg/dL
Bezafibrate	80 mg/dL
Bile Acids (Cholic Acid)	5 mg/dL
Conjugated bilirubin	30 mg/dL
Creatinine	10 mg/dL
Diphenhydramine	1 mg/dL
Dopamine	10 mg/dL
Fructose	1000 mg/dL
Furosemide	6 mg/dL
Gentisic acid	12 mg/dL
Glibenclamide	2 mg/dL
Hemoglobin	500 mg/dL
Ibuprofen	55 mg/dL
Indomethacin	10 mg/dL
Lactitol	1000 mg/dL
Lactose	1000 mg/dL
Levo – Dopa	3 mg/dL
Maltitol	1000 mg/dL

Potential Interferent	Highest concentration tested that did not cause interference
Maltose	1000 mg/dL
Mannitol	1000 mg/dL
Methyl - Dopa	5 mg/dL
Nicotinic acid	200 mg/dL
Probenecid	60 mg/dL
Quinidine hydrochloride monohydrate	20 mg/dL
Salicylic acid	60 mg/dL
Sorbitol	1000 mg/dL
Sulfamethoxazole	120 mg/dL
Total Protein (gamma-Globulin)	12000 mg/dL
Triglycerides	703 mg/dL
Trimethoprim	45 mg/dL
Unconjugated bilirubin	20 mg/dL
Urea	600 mg/dL
Uric acid	15 mg/dL
Xylitol	1000 mg/dL
Xylose	1000 mg/dL

The sponsor includes the following limitations in the labeling for the FORA ADVANCED GD40 Glucose, β -Ketone and Cholesterol Monitoring System which were developed to explain the interferences for all three test strips based on the analytical specificity data for the cholesterol strips described above and based on the analytical specificity data for the ketones and glucose strips described in k161738:

- Acetaminophen in your blood >6.25 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 healthcare provider.
- 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 provider.
- Xylose: Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can give falsely elevated results.

- Reduced glutathione level to > 30 mg/dL may affect the glucose results. If you are unsure, then ask your healthcare provider.
- Pralidoxime iodide level to >5 mg/dL may affect the glucose results. If you are unsure, then ask your healthcare provider.
- FOR CHOLESTEROL ONLY (This limitation does not apply to testing glucose or ketones levels.)
 - Users with very high triglyceride levels (>700 mg/dL) should not use this device to test their cholesterol level.
 - All other users should only check their cholesterol levels first thing in the morning before they have eaten to avoid possible incorrect cholesterol results due to very high triglyceride levels. Triglyceride levels above 700 mg/dL may lead to incorrect cholesterol results. Triglyceride levels may be higher after a meal. If you have questions about your triglyceride level, talk to your healthcare professional.

4. Assay Reportable Range:

The sponsor claims a measuring range of 100 – 400 mg/dL for cholesterol. This range was supported by the results from the linearity, precision, limit of detection, and accuracy studies.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability

FORA ADVANCED GD40 Glucose, β -Ketone and Cholesterol Monitoring System is CRMLN certified for total cholesterol using whole blood samples.

Stability

The FORA ADVANCED GD40 Glucose, β -Ketone and Cholesterol strips are provided packaged in vials and as individually wrapped single strips.

The study protocol and acceptance criteria for test strips in vials were reviewed and found acceptable to support the product stability claims:

Cholesterol Test Strips in Vials:

- Closed-vial (shelf-life) – 18 months at the recommended storage conditions of 35.6°F to 86.0°F (2°C - 30°C) and 10%-85% relative humidity
- Opened-vial – 180 days at the recommended storage conditions of 35.6°F to 86.0°F (2°C - 30°C) and 10%-85% relative humidity

Individually Wrapped Cholesterol Test Strips

- Sealed Wrapper (shelf-life) - 24 months under the recommended storage conditions of 35.6°F to 86.0°F (2°C - 30°C) and 10%-85% relative humidity

6. Detection Limit:

The detection limits studies of the candidate device's cholesterol assay were conducted in accordance with CLSI EP17-A2.

LoB: To estimate the LoB, the sponsor used four (4) meters, two (2) cholesterol strip lots, and five (5) different analyte-free (blank) venous blood samples. Each blank sample was analyzed in replicates of four (4) on three (3) different days. The limit of blank was estimated by interpolation from the ranked values to be 15 mg/dL.

LoD: To estimate the LoD, the sponsor used four (4) meters, two (2) cholesterol strip lots, and venous blood samples at five (5) different concentrations. Each sample was analyzed in replicates of four (4) on three (3) different days. The data was evaluated using the parametric analysis recommended in CLSI EP17-A2 and the LoD was estimated to be 26 mg/dL.

LoQ: To estimate the LoQ, the sponsor used two (2) meters, two (2) cholesterol strip lots, and venous blood samples at nine (9) different concentrations. Each sample was tested in replicates of two (2) on twenty (20) different days. The LoQ estimate for each lot was determined as the measurand concentration at the intersection of its power function model fit line with the imprecision goal of a 10% CV. The LoQ of total cholesterol was 97 mg/dL.

The sponsor chose 100 mg/dL as the lowest reportable cholesterol concentration.

7. Assay Cut-Off:

Not applicable.

8. Accuracy (Instrument):

See method comparison study

9. Carry-Over:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

A method comparison study was conducted to determine the accuracy performance of the candidate device's cholesterol test. The study included 408 participants at three (3) sites (136 subjects per site).

Of the participants, 223 (54.7%) were male and 185 (45.3%) were female. The ages of the participants were from 22 to 74 years with a mean age of 55.5 years and adequately represented the intended use population.

Participants self-collected a capillary blood sample for cholesterol testing. After testing, nursing staff collected a venous blood sample for comparison on the comparator method. Total cholesterol levels were between 106 mg/dL and 388 mg/dL. Three (3) reagent (strip) lots were used in the study.

The differences between the self-collected results and the comparator method were estimated according to the following equation:

$$\frac{\text{Meter Value (mg/dL/mmol/L)} - \text{Comparator Method (mg/dL/mmol/L)}}{\text{Comparator Method Value (mg/dL/mmol/L)}} \times 100\% = \% \text{ Diff}$$

Results are summarized in the following table:

	# Subjects	Test results within $\pm$			
Total cholesterol	408	5%	10%	15%	20%
		407/408 (99.8%)	408/408 (100%)	408/408 (100%)	408/408 (100%)

The sponsor also performed a linear regression analysis, summarized below.

Total cholesterol concentration (mg/dL)						
Test results	n	Slope	95% CI slope	Intercept	95% CI intercept	R ²
All	408	0.992	0.983 to 1.002	1.067	-1.036 to 3.171	0.991
Site A, Lot 1	136	0.983	0.967 to 1.000	3.107	-0.554 to 6.769	0.991
Site B, Lot 2	136	0.996	0.980 to 1.013	0.121	-3.655 to 3.897	0.991
Site C, Lot 3	136	0.999	0.982 to 1.015	-0.387	-4.009 to 3.236	0.991

Usability was also evaluated in the accuracy study. After the study, participants were given a questionnaire and asked to rate the ease of use of the system and the clarity of the instructions. The survey results demonstrated that lay users found the system and instructions for use to be adequate.

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

A “mock” study was conducted to evaluate the lay user’s ability to understand and distinguish glucose and cholesterol results obtained with the same meter. The study included 500 participants at 3 sites. Participants were randomly divided into five groups and were provided with samples with varying levels of cholesterol and glucose combinations. Observers noted whether participants could correctly identify and distinguish between cholesterol and glucose results.

Analysis of the number of participants who correctly differentiated glucose and cholesterol measurements, as compared to the result observed by the observer, showed 100% correct results across all 3 sites.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The National Heart, Lung and Blood Institute issued the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP III) in 2002. The ATP III report presents NCEP’s clinical guidelines for cholesterol testing and management, and recommends the following classifications for cholesterol concentration levels:

Reference range for total cholesterol		
Analyte	Concentration, mg/dL	ATP III Classification
Total cholesterol	< 200	Desirable
	200 - 239	Borderline high
	≥ 240	High

Source: Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP III). National Cholesterol Education Program, National Heart, Lung, and Blood Institute, National Institutes of Health, NIH Publication No. 02-5215, September 2002.

F Other Supportive Instrument Performance Characteristics Data:

1. Hematocrit Study:

A hematocrit study was performed to verify that the total cholesterol measurement is not affected by hematocrit levels between the range of 10% to 70% over a wide range of total cholesterol levels. Ten (10) meters, (one) 1 lot of test strips, and venous blood samples at concentrations of 153 mg/dL, 182 mg/dL, 264 mg/dL and 334 mg/dL were used in the study. Hematocrit was adjusted to 10%, 20%, 30%, 40%, 50%, 60%, and 70%. The % bias at each hematocrit level relative to the nominal hematocrit level of 40% was calculated. The acceptance criterion was that

the total cholesterol bias be within $\pm 10\%$ compared to the nominal condition of hematocrit at 40%. The data provided supports the claimed hematocrit range of 20 – 70%.

2. Altitude Effect Evaluation:

An altitude effect study was conducted to evaluate the effect of different altitudes on cholesterol measurements. A glove box system, which simulates three altitude conditions from sea level to 3500 meters (11,484 feet), was used. Venous whole blood samples from healthy donors at five (5) different levels of cholesterol (119, 182, 228, 262, and 345 mg/dL) were tested at various atmospheric pressures which simulate different altitudes. Four (4) candidate devices were used to measure cholesterol and the results were compared to the comparator method and to the results at sea level. The sponsor's acceptance criterion was that the bias to the comparator method and to sea level be $\leq \pm 10\%$. The acceptance criteria were satisfied and supported the sponsor's claimed altitude of 10742 feet (3274 meters).

3. Temperature and Humidity Studies:

The operating conditions for the glucose and β -ketones test system were established in k161738. The operating conditions for the cholesterol functionality were assessed in the current submission and demonstrated that the cholesterol assay functions as intended within the labeled operating conditions of 50-104° F (10-40° C) and relative humidity of 10-85%.

4. Sample Volume Study:

A sample volume study was conducted on the FORA ADVANCED GD40 Glucose, β -Ketone and Cholesterol Monitoring System to verify the robustness of the system to variations in the intended five (5) μ L sample volume and to test the meter's functionality at detecting insufficient volumes. Five (5) meters and three (3) different venous blood samples at different levels of total cholesterol (140, 240, and 340 mg/dL) were used in the study. Sample volumes from 4.7 μ L to 5.2 μ L were tested under normal operating conditions (25°C (77°F) at 60% RH). Reported results were within $\pm 5\%$ bias and sample volumes between 4.7 μ L and 4.8 μ L provided an error for insufficient volume in 100% of the readings. Sixty percent of the (60%) readings for the 4.9 μ L volume provided a result and 40% provided an error for insufficient volume. The results support the recommended 5 μ L volume.

5. Infection Control Studies:

The FORA ADVANCED GD40 Glucose, β -Ketone and Cholesterol Monitoring System is intended for single-patient use only. Disinfection efficacy studies were previously performed (k161738) on the exterior materials of the meter by an outside commercial laboratory service to demonstrate complete inactivation of hepatitis B virus (HBV) with Micro-Kill Wipes (EPA Reg. No. 59894-10-37549). Robustness studies were performed by the sponsor (in k161738 for glucose and ketones and in the current submission for cholesterol) demonstrating that there was no change in performance or in external materials of the meters after 10,950 cleaning and disinfection cycles with Micro-Kill Wipes. The robustness studies were designed to simulate 5 years of single-patient use. The labeling was reviewed for adequate instructions for the cleaning and disinfection procedures.

6. Readability Evaluation:

A readability study was conducted on the system manual, test strip manuals, quick user guide, and controls package inserts demonstrating that they are written at an 8th grade reading level or less.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.