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

A. 510(k) Number:

k101299

B. Purpose for Submission:

New blood glucose monitoring system (new Aviva Plus glucose test strips with a modified GDH-PQQ methodology are intended to be used with the cleared ACCU-CHECK Aviva meter)

C. Measurand:

Capillary whole blood Glucose

D. Type of Test:

Quantitative amperometric assay, glucose dehydrogenase (mutant GDH- PQQ)

E. Applicant:

Roche Diagnostics

F. Proprietary and Established Names:

ACCU-CHEK Aviva Plus 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. Indication(s) for use:

   The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or palm. The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

   The ACCU-CHEK Aviva Plus 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. The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

   The ACCU-CHEK Aviva Plus Test Strips are for use with the ACCU-CHEK Aviva Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or palm.

3. Special conditions for use statement(s):

   - For in vitro diagnostic use only
   - Device is for over-the-counter (single patient use) only and should not be shared
   - Not intended for use on neonates
   - Not for the 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

4. Special instrument requirements:

   ACCU-CHEK Aviva Blood Glucose Meter

I. Device Description:

The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System consists of:

- ACCU-CHEK Aviva Blood Glucose Meter (cleared under k060620)
- ACCU-CHEK Aviva Plus test strips with modified GDH – PQQ technology
- Code key
- ACCU-CHEK MultiClix Lancing Device with 12 Lancets

ACCU-CHEK Aviva Control solution is required but sold separately

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ACCU-CHEK Aviva

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

   k060620

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indications for Use	Same	For the quantitative measurement of glucose in fresh capillary whole blood
Measuring Range	20 – 600 mg/dL	10 – 600 mg/dL
Hematocrit Range	10 – 65%	10 – 70%
Detection Method	Same	Amperometry
Measuring Time	Same	5 seconds
Sample Volume	Same	0.6 µL
Capillary Sample Sites	Fingertip, forearm, upper arm, palm	Fingertip, forearm, upper arm, palm thigh, calf
Coding	Same	Code Key
Memory	Same	500 stored results

Differences		
Item	Device	Predicate
Enzyme	Modified Glucose dehydrogenase pyrroloquinoline quinone (GDH-PQQ)	Glucose dehydrogenase pyrroloquinoline quinone (GDH-PQQ)
Intended Users	Single patient use	Single patient and healthcare professional
Sample Type	Capillary blood only	Rx use: capillary, venous, arterial, and neonatal blood OTC use: capillary blood only

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

- CLSI EP7 - Interference Testing in Clinical Chemistry
- CLSI EP5 – Evaluation of Precision Performance of Quantitative Measurement Methods
- ISO15197:2003- In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

L. Test Principle:

When an ACCU-CHEK® Aviva Plus test strip is inserted into the ACCU-CHEK® Aviva meter, a small alternating current (AC) is applied until the application of blood causes a spike in the conductivity to be observed at the measurement and sample - sufficiency electrodes. Both are used to assure an adequate sample has been applied. The meter then applies a series of AC voltages at four frequencies and reads the AC responses. These carry information about the sample type and environmental temperature; they also allow the system to perform various internal quality checks. After the AC measures are completed, a small (DC) voltage is applied and current is observed which is proportionate to the glucose. The AC and DC information are then combined to provide a hematocrit and temperature compensated glucose result.

The enzyme on the test strip, a variant of glucose dehydrogenase, converts the glucose in the blood sample to gluconolactone. This reaction creates a harmless DC electrical current that the meter interprets for the blood glucose result. The sample and environmental conditions are also evaluated using a small AC signal.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Repeatability Precision (Within Vial)

   A total of 50 individual strip vials per each of three strip lots were used for data collection. These vials were separated into 5 sets of 10 vials each and assigned to 1 of 5 venous blood samples at varying concentrations.

   Ten runs were performed on each sample, with an n = l0 replicates collected per vial/strip lot. This resulted in a total of 100 replicates collected for each strip lot and glucose level tested. Results are summarized in the table below.

Level	1			2			3		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean	42.7	42.5	40.9	90.0	90.7	87.1	121.9	121.2	120.4
SD	2.1	1.5	1.5	2.9	3.9	2.8	4.1	5.5	4.0
CV(%)	4.8	3.4	3.6	3.3	4.3	3.3	3.3	4.6	3.3
n	100	100	100	100	100	100	100	100	100

Level	4			5		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean	185.9	182.4	183.1	312.8	306.5	309.7
SD	6.3	6.6	5.4	10.7	12.9	10.2
CV(%)	3.4	3.6	3.0	3.4	4.2	3.3
n	100	100	100	100	100	100

Intermediate Precision (Day-to-Day)

Intermediate precision was assessed by analyzing three levels of commercial linearity controls. Results were collected over 10 consecutive days by two operators using three strip lots. Results are summarized in the table below.

Level	1	2	3
mean	45.1	118.7	307.4
SD	1.4	3.0	7.7
CV (%)	3.1	2.5	2.5
n	300	300	300

b. Linearity/assay reportable range:

Linearity was evaluated using 8 spiked whole blood samples with glucose concentrations ranging from 18 to 632 mg/dL (18, 38, 63, 81, 153, 314, 470, and 632 mg/dL) as measured by the reference method. Per lot, each sample was measured 4 times out of 8 strip vials for a total of 32 replicates per level.

Results are summarized in the table below:

Strip Lot	Slope	Intercept	Corr Coeff (r)	Range of recoveries
1	0.992	-0.649	1.000	98 – 105%
2	0.977	-0.842	1.000	96 – 103%
3	1.011	-0.415	1.000	98 – 107%

The claimed range of measurement for this device is 20 to 600 mg/dL glucose.

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

The Aviva Plus system is calibrated to a hexokinase method on a laboratory analyzer. A method comparison was performed using this method as the comparative method. See Comparison studies in 2a below.

The controls recommended for the ACCU-CHEK Aviva Plus Blood Glucose Monitoring System were cleared under k043474.

The sponsor provided a protocol and acceptance criteria to verify the closed-vial stability (shelf life) and open vial stability of the test strips. The stability protocols and acceptance criteria were reviewed and found to be acceptable. The sponsor claims a closed-vial (shelf life) and open-vial stability of 18 months when stored at 36 – 86° F (2 – 30° C)

d. Detection limit:

The claimed reportable range for the system is 20 – 600 mg/dL. This range was verified by the linearity study (M.1.b) above.

e. Analytical specificity:

To assess potential interference, whole blood samples were spiked with glucose at concentrations of approximately 25, 55, 120, 350, and 500 mg/dL and split into a control sample and a test sample. Various endogenous and exogenous substances were then added to the test sample only. Concentrations tested were at least three times the upper therapeutic level (for drugs) or three times the highest expected concentration (for endogenous substances). Concentrations listed in CLSI EP7-A2 were used when available. For substances not listed in CLSI EP7-A2, other published references were consulted. Each combination of glucose concentration and interferent concentration was analyzed 16 times per strip lot using three strip lots for a total of 48 measurements per each combination of glucose and interferent. The % difference between the test sample and the control sample was calculated. The sponsor defines no significant interference as ≤ 10%.

Three compounds were found to cause significant interference:

Compound Name	**Concentration at Which Significant Interference Criteria was Seen (mg/dL)**
Triglycerides	> 1800
Galactose	> 15
Ascorbic Acid	> 3

The sponsor includes the following in the limitations section of the labeling:

- Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
- Blood concentrations of galactose >15 mg/dL will cause overestimation of blood glucose results.
- Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.

The remaining compounds tested were found to not cause significant interference, as follows:

Compound Name	Concentration at Which No Significant Interference Criteria was Seen (mg/dL)
β - Carotene	0.6
5-Fluorocytosine	30
Acarbose	60
Acetaminophen	20
Acetazolamide	6
Acetone	60
Acetylprocainamide	15
Acetylsalicylic Acid	60
Acyclovir	5
Albumin	5000
Albuterol	25
Allopurinol	5
Aminocaproic Acid	0.08
Amiodarone HCI	5
Amitriptyline HCI	1
Amoxapine	0.1
Amoxicillin	600
Ampicillin	5.3
Astemizole	1
Atropine	1
Bile Acids	1.5
Buspirone HCI	1
Caffeine	10

Compound Name	Concentration at Which No Significant Interference Criteria was Seen (mg/dL)
Captopril	0.5
Carbamazepine	3
Cefaclor	200
Cefadroxil	10.5
Cephalexin	32
Cephalothin Sodium	200
Cetirizin Dihydrochloride	1
Chenodeoxycholic Acid	3
Chlorothiazide	2
Chlorpropamide	80
Cholesterol	500
Cholic Acid	2.4
Cimetidine	10
Citric Acid	30
Clindamycin	4.5
Clonidine HCI	2
Conjugated Bilirubin	15
Creatinine	30
Cyclophosphamide	37.5
Desipramine HCI	0.1
Dexamethasone	0.09
Dextromethorphan HBr	1
Diclofenac	5
Dicumarol	20
Digoxin	1

Diltiazem	20
Diphenhydramine HCl	1
Dipyrone	11
Disopyramide	5
DL Dopa	2.8
DL-Tyrosine	24
DL-β-Hydroxybutyric Acid	100
D-Mannitol	600
D-Mannose	10
D-Norpropoxyphene Maleate	1
Dopamine HCl	1.5
Doxazosin Mesylate	1
Doxycycline Hyclate	3
D-Penicillamine	2.4
D-Sorbitol	70
EDTA Calcium Disodium Salt	180
Enalapril	8
Ephedrine	1
Equilin	15
Erythromycin	60
Estradiol	0.1
Estrone	1
Ethanol	350
Ethosuximide	25
Ethyl Acetoacetate	20
Ethylene Glycol	5
Famotidine	0.6
Felodipine	5
Fenofibrate	5
Fenoprofen	20
Flecainide Acetate	1
Fluoxetine HCl	12
Flurbiprofen	5
Fructose	250
Furosemide	6
Galactose-1-phosphate	5
Gamma Globulins	3000
Gemfibrozil	15
Gentamicin Sulfate	3.6
Gentisic Acid	50
Glimepiride	1
Glipizide	8
Glucosamine	450

Glybenclamide	1.5
Glycerol	10
Hemoglobin	500
Heparin Lithium	8000 U/dL
Heparin Sodium	8000 U/dL
Humulin N	20 U/dL
Humulin R	20 U/dL
Hydrochlorothiazide	0.61
Hydrocortisone	1
Hydroxychloroquine Sulfate	4
Ibandronic Acid	0.5
Ibuprofen	40
Indomethacin	5
Isoniazid	5
Kanamycin	6
Lactic Acid	100
Lactose	10
L-Cysteine	5
L-Cystine	50
Lecithin	500
L-Glutathione, oxidized	183.9
L-Glutathione, reduced	12.3
Lidocaine	1.2
Lisinopril	1
lodoacetate	35
Loratadine	1
Lovastatin	0.4
L-Phenylalanine	50
L-Thyroxine	5
Magnesium Sulfate	26
Metaproterenol	1.81
Metformin	50
Methyl Dopa	2.5
Methylhydroxy progesterone	50
Metoclopramide HCl	0.13
Metoprolol Tartrate	0.7
Mexiletine HCl	1
Misoprostol	0.8
Nadolol	2
Naproxen	100
Neostigmine Bromide	0.2
Neostigmine Methyl Sulfate	0.2

Nicotine	2
Nifedipine	40
Nitrofurantoin	4
Nordoxepin HCI	5
Normethyl-(±)-verapamil HCI	1
Nortriptyline HCI	0.3
Oleic Acid	35
Omeprazole	0.52
Oxalic Acid	20
Palmitic Acid	150
Penicillin G	15
Phenelzine Sulfate	0.5
Phenytoin	10
Pindolol	0.5
Pioglitazone	5
Piroxicam	10
Polysorbate 80	24
Potassium Chloride	50
Pralidoxime Iodide (PAM)	25
Primidone	5
Probenecid	60
Procainamide HCI	10
Propranolol HCI	1
Pseudoephedrine	1
Pyridoxine HCI (Vitamin B6 HCl)	3
Pyruvic acid	4
Quinine Sulfate	4.8
Ramipril	3.58
Ranitidine HCI	20
Repaglinide	5
Rifampicin	8
Rosiglitazone	5
Salicylic Acid	60
Sodium Bicarbonate	336
Stearic Acid	15
Streptomycin Sulfate	15
Sucrose	500
Terfenadine	25
Tetracycline HCI	10
Theophylline	25
Thioridazine HCI	4
Tobramycin	3.6
Tolazamide	200
Tolbutamide	100
Trazodone HCI	2
Triamterene	6
Trimethoprim	6
Unconjugated Bilirubin	40
Urea	600
Uric Acid	40
Valproic Acid	50
Vancomycin HCI	20
Verapamil HCI	1
Vitamin B12	1
Vitamin E	20
Voluven	800
Warfarin	10
Xylitol	200
Xylose	100
Zenapax (Daclizumab)	10

Hematocrit study:
The effect of different hematocrit levels was evaluated using venous whole blood samples with hematocrit levels of 10 – 65% (10,15, 20, 25, 30, 43, 50, 55, 60, and 65%) spiked with glucose to achieve target concentrations of 25, 55, 120, 350, and 500 mg/dL. Three strip lots were evaluated, and there were 30 measurements for each combination of strip lot, glucose concentration, and hematocrit level tested. The results demonstrated that the ACCU-CHEK Aviva Plus Blood Glucose Monitoring System produces accurate results over the claimed hematocrit range of 10 – 65%.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

System Accuracy:

To assess system accuracy, the ACCU-CHEK Aviva Plus Blood Glucose Monitoring System was compared to a hexokinase – based reference method. All of the samples were capillary fingersticks collected by a trained technician. Additional blood from the same fingerstick was collected for the reference measurement.

If native samples could not be collected for glucose concentrations <50 mg/dL or >400 mg/dL, then samples could be collected into a Lithium heparin anticoagulant tube and allowed to age in order to achieve a glucose concentration <50 mg/dL or spiked with glucose to achieve a glucose concentration >400 mg/dL.

Five samples were allowed to glycolyze to achieve a concentration less than 50 mg/dL and four samples were spiked to achieve a concentration greater than 400 mg/dL.

Linear regression based on single glucose measurements produced the following:

Lot	n	Range of values mg/dL	Slope	Slope 95% CI	Intercept	Intercept 95% CI	r	Std. Error
1	100	20-529	1.026	(1.001, 1.051)	-3.1	(-8.4, 2.2)	0.992	14.6
2	100	22-511	1.042	(1.017, 1.067)	-3.7	(-8.8, 1.4)	0.993	14
3	100	19-542	1.018	(0.993, 1.043)	-2.4	(-7.6, 2.8)	0.992	14.6

System accuracy results for glucose concentration <75 mg/dL

Strip Lot	Within ±5 mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
1	15/16 (93.8%)	16/16 (100%)	16/16 (100%)
2	14/16 (87.5%)	16/16 (100%)	16/16 (100%)
3	12/16 (75%)	16/16 (100%)	16/16 (100%)
Combined	41/48 (85.4%)	48/48 (100%)	48/48 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Strip Lot	Within ±5%	Within ± 10%	Within ± 15%	Within ±20 %
1	53/84 (63.1%)	74/84 (88.1%)	82/84 (97.6%)	84/84 (100%)
2	44/84 (52.4%)	73/84 (86.9%)	81/84 (96.4%)	83/84 (98.8%)
3	50/84 (59.5%)	75/84 (89.3%)	83/84 (98.8%)	83/84 (98.8%)
Combined	147/252 (58.3%)	222/252 (88.1%)	246/252 (97.6%)	250/252 (99.2%)

b. Matrix comparison:

Not applicable. Fresh capillary whole blood is the only acceptable matrix.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

User results with capillary blood from the fingertip

A user performance study was performed to compare the lay user self-test results to the hexokinase reference method. The study was performed in 2 clinical sites with samples from 195 subjects using three lots of test strips. Each subject was asked to read the English version of the First Time Guide and Owner's Booklet, which will be provided to users when the device is marketed. Subjects were not allowed to practice testing with controls or blood prior to performing their own fingerstick blood glucose test.

Linear regression analysis results based on single glucose measurements are summarized below:

n	Range of values mg/dL	Slope	Slope 95% CI	Intercept	Intercept 95% CI	r	Std. Error
195	41-472	0.969	(.949, .989)	2.3	(-1.3, 5.9)	0.989	11.6

System accuracy results for glucose concentration <75 mg/dL

Within ±5 mg/dL	Within ±10mg/dL	Within ±15mg/dL
23/29 (79.3%)	29/29 (100%)	29/29 (100%)

System accuracy results for glucose concentration >75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
94/166 (56.6%)	152/166 (91.6%)	164/166 (98.8%)	165/166 (99.4%)

User results with capillary blood from alternate sites

A user performance study was performed to compare the lay user self-test results to the hexokinase reference method. The study was performed in 2 clinical sites. For samples collected from the palm, 153 subjects collected capillary blood from the thenar site and 161 subjects collected blood from the hypothenar site. No significant difference was seen between the thenar and hypothenar sites, and they were combined for a total of 314 measurements from the palm. Forearm samples were collected by 155 subjects and upper arm samples were collected by 156 subjects. Each subject was asked to read the English version of the First Time Guide and Owner's Booklet, which will be provided to users when the device is marketed. Subjects were not allowed to practice testing with controls or blood prior to performing their own fingerstick blood glucose test.

Linear regression analysis based on single glucose measurements are summarized below:

Alternate Site	**n**	**Range of values mg/dL**	**Slope**	**Slope 95% CI**	**Intercept**	**Intercept 95% CI**	**r**	**Std. Error**
Palm	314	60-439	0.983	(0.963, 1.003)	0.1	(-2.9, 3.1)	0.984	11.6
Forearm	155	61-381	1.004	(0.967, 1.041)	-1.9	(-8.1, 4.3)	0.975	16.3
Upper Arm	156	61-381	0.929	(0.896, 0.962)	8.4	(2.8, 14)	0.976	14.8

System accuracy results for glucose concentration <75 mg/dL

Alternative Site	Within ±5 mg/dL	Within ± 10mg/dL	Within ±15mg/dL
Palm	8/11 (73%)	11/11 (100%)	11/11 (100%)
Forearm	3/6 (50%)	5/6 (83%)	6/6 (100%)
Upper Arm	4/6 (67%)	5/6 (83%)	6/6 (100%)

System accuracy results for glucose concentration ≥75 mg/dL

Alternate Site	Within ±5%	Within ± 10%	Within ± 15%	Within ± 20%
Palm	158/303 (52%)	242/303 (80%)	280/303 (92%)	299/303 (99%)
Forearm	64/149 (43%)	104/149 (70%)	136/149 (91%)	147/149 (99%)
Upper Arm	66/150 (44%)	109/150 (73%)	135/150 (90%)	146/150 (97%)

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   The sponsor states the following in their labeling:

   Expected Values

   The normal fasting glucose level for an adult without diabetes is below 100 mg/dl [1, 2.] . Two hours after meals, the normal blood glucose level for a non-diabetic adult is less than 140 mg/dl [2.] For people with diabetes: please consult your healthcare professional for the blood glucose level appropriate for you. You should treat your low or high blood glucose as recommended by your healthcare professional.

   References:

[1]American Diabetes Association: Diagnosis and Classification of Diabetes Mellitus (Position Statement). Diabetes Care 34 (Supp. 1) S66, 2011

[2]Tietz Fundamentals of Clinical Chemistry, 6th Edition, Edited by Burtis CA and Ashwood ED, W. B. Saunders Co., Philadelphia, PA, 2008, p. 849

N. Instrument Name:

ACCU-CHEK Aviva Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and requires a sample volume of 0.6 uL.

   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:

   This device is intended to be used with capillary whole blood from the finger, palm, forearm, and upper arm only. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   The meter is coded by the user by inserting a code key. The labeling instructs the user to leave the code key in the meter until a new box of test strips is opened and to change the

code key each time a new box of test strips is opened.

6. Quality Control:

   Controls are not included in the ACCU-CHEK Aviva Plus Blood Glucose Monitoring System starter kit, but the labeling explains how users can obtain two levels of controls. The labeling also provides recommendations on when to test control materials. The meter can recognize a control solution automatically and control results are not stored in memory. An acceptable range for each control level is printed on the test strip vial label. If the control values fall outside these ranges, the user is referred to a troubleshooting chart which includes information on how to contact the Customer Care Service Center.

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

1. Infection Control studies: The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System is intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter and lancing device by an outside commercial testing facility demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Super Sani-Wipes (EPA Registration Number 9480-4). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials for the meter and lancing device after 260 cleanings and 260 disinfection steps with Super Sani-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.

2. A usability study was performed to assess the readability of the labeling by recruiting untrained lay users who were provided with the test kit containing labeling for the US market. These lay users also completed a questionnaire regarding the clarity of the instructions and the ease of use of the device. The majority of the users responded that they understood the instructions and were able to successfully operate the device.

3. Flesch-Kincaid readability assessment was conducted for the meter user's manual and test strip package insert and were found to be 7.5 and 8.2, respectively.

4. The Customer Care Service Center is available 24/7, 365 days a year. The toll free phone number is 1-800-858-8072.

5. The sponsor claims an operating condition range of 14 – 40° C and 10 – 80% relative humidity. Combinations of the claimed temperature and humidity operating conditions were evaluated by measuring whole blood samples at target glucose concentrations of 70, 120, and 250 mg/dL and comparing the meter results to a reference method. The results demonstrated that the system produces accurate results over the claimed range of operating conditions.

6. To evaluate the effects of altitude, glycolyzed venous blood samples from three donors were spiked to glucose concentrations of approximately 40, 90, and 400 mg/dL and tested

in a glove box chamber set to simulate atmospheric conditions at 10,000 feet. Three lots of glucose strips were tested in six runs with three replicates per run. This resulted in a total of 18 replicates for each combination of strip lot, glucose level, and donor and a total of 54 replicates overall. These studies demonstrated that altitudes up to 10,000 feet have no significant effect on blood glucose measurements

7. Electromagnetic Compatibility (EMC) testing was performed and found to be adequate in k043474. The Aviva meter in this submission is identical to the one reviewed in k043474.

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.