510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:

k050182

B. Purpose For Submission:

Premarket Notification 510(k) of intention to manufacture and market the Biomedix, Inc. Q. STEPS Biometer G/C Dual Monitoring System

C. Analyte:

Whole Blood Glucose
Whole Blood Cholesterol

D. Type of Test:

Quantitative, utilizing Glucose Oxidase technology.
Quantitative, utilizing Cholesterol Oxidase technology.

E. Applicant:

Biomedix, Inc.

F. Proprietary and Established Names:

Q. STEPS™ Biometer G/C Dual Monitoring System.

G. Regulatory Information:

1. Regulation section:

Regulation Number	Standard Product Nomenclature	Panel	Product Code	Class
862.1345	System, Test, Blood Glucose, Over The Counter	Chemistry (75)	NBW	II
862.1345	Glucose Oxidase, Glucose	Chemistry (75)	CGA	II
862.1175	Enzymatic Esterase-Oxidase, Cholesterol	Chemistry (75)	CHH	I
862.1660	Single (Specified) Analyte Controls (Assayed and Unassayed)	Chemistry (75)	JJX	I

H. Intended Use:

1. Intended use(s):
   See Indications for use below.

2. Indication(s) for use:
   The Q. STEPS Biometer G/C Dual Monitoring System is intended for use with Q.STEPS Glucose and Cholesterol Test Strips with Q. STEPS Biometer G/C by healthcare professionals and home users. Q. STEPS Biometer G/C System provides a quantitative measurement of Glucose and Cholesterol in whole blood from the fingertips. The Glucose measurements are used in helping the management of carbohydrate metabolism disorders including diabetes mellitus, idiopathic hypoglycemia and pancreatis islet cell tumors. Cholesterol measurements are used in the management of disorders involving excess cholesterol in the blood, lipid and lipoprotein metabolism disorders.

3. Special condition for use statement(s):
   Provides plasma equivalent results.

4. Special instrument Requirements:
   Q. STEPS Biometer G/C Dual Monitoring System.

I. Device Description:

The Q. STEPS™ Biometer G/C Dual Monitoring System uses enzymatic electrochemical biosensor technology to measure whole blood glucose and cholesterol levels. When finger blood is applied to the test spot of the biosensor (test strip) a reduction-oxidation reaction occurs. The oxidase of D-Glucose or Cholesterol which is catalyzed by Glucose Oxidase or by Cholesterol Oxidase respectively, causes an electron transfer at the electrode (silver) surface; and therefore, the magnitude of the current produced is proportional to the glucose or cholesterol concentration in the blood. The Biometer G/C uses that current to quantify the glucose and the cholesterol levels in the blood, and then display on the readout of the monitor.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   One Touch Basic Blood Glucose Monitoring System
   PTS Panels Lipid Panel Test Strips

2. Predicate K number(s):
   k031472
   k023558

3. Comparison with Predicate:

Substantial Equivalence Comparison Glucose

Similarities

Item	Devices k050182	Predicate k031472
Intended Use	Q. STEPS™ Biometer G/C Dual Monitoring System (Glucose Side Sensor) Intended to be used with Q.STEPS™ Biometer G/C and Q. STEPS™ Glucose Test Strips for the quantitative measurement of glucose in fresh capillary whole blood from the fingertip. For professionals and Diabetes patients use.	One Touch Basis System Intended to be used with One Touch ® basic and One Touch® Test Strips for the quantitative measurement of glucose in fresh capillary whole blood from fingertip. For professionals and Diabetes patients use.
Test Principle	Based on Glucose Oxidase oxidation reduction to convert glucose into gluconic acid.	Based on Glucose Oxidase oxidation reduction to convert glucose into gluconic acid.
Labeling Instruction Regarding Response to Unusual Results	Test should be run with liquid quality control material, Q. STEPS™ Control Solution whenever a new vial of test strip is opened or unusual blood test result is obtained.	Test should be run with liquid quality control material, One Touch® Control Solution whenever a new vial of test strip is opened or unusual blood test result is obtained.
Meter Functional Test	A check strip is provided to ensure the system is working properly	A check strip is provided to ensure the system is working properly
Test Strips Storage Condition	Must be stored in the original vial with the cap tightly closed. Stored in a cool dry place not above 86°F (36°C) and away from heat and direct sunlight, not refrigerated.	Must be stored in the original vial with the cap tightly closed. Stored in a cool dry place not above 86°F (36°C) and away from heat and direct sunlight, not refrigerated.
Strip Shelf Life	After opening the vial, 4 months	After opening the vial, 4 months

Differences

Item	Devices k050182	Predicate k031472
Methodology	Amperometric	Photometric
Test Recall Memory	99 test results	75 test results memory capacity.
Blood Sample Volume Reaction Time	Minimum is 5µl/30 seconds	Minimum is 10 µl / 45 seconds
Physical Characteristics	The test spot is on the side of the test strip and is a shape of half-a-circle.	The test spot is on the center of the test strip and is in the shape of a circle.

Substantial Equivalence Comparison Cholesterol

Similarities

Item	Devices k050182	Predicate k023558
Intended Use	The Q. STEPS™ Test Strip is intended to measure cholesterol in whole blood on the G/C Dual Monitoring System. For Professionals and Diabetes patients use.	The Lipid Panel Test Strips are intended to measure cholesterol, HDL and triglycerides in whole blood on a BIOScanner Plus (CardioChek Brand) analyzer. For Professionals and home user.
Matrix	Finger Whole Blood	Finger Whole Blood
Result Display	Directly displays results without requiring calculation.	Directly displays results without requiring calculation.
Enzymatic reaction	Cholesterol Oxidase and Esterase Reaction	Cholesterol Oxidase and Esterase Reaction
Physical Characteristics	Test strip with circular spot	Test strip with circular spot
Calibration Chip	It contains a lot specific electronically erasable, programmable read-only memory (EEPROM) chip in the same package with the strips. The EEPROM chip has the curve information programmed into it and based on a multipoint curve and is established for each lot. The user inserts this chip into the meter with each new lot of test strips.	It contains a lot specific electronically erasable, programmable read-only memory (EEPROM) chip in the same package with the strips. The EEPROM chip has the curve information programmed into it and based on a multipoint curve and is established for each lot. The user inserts this chip into the meter with each new lot of test strips.
Device Storage	2-30°C	2-30°C

Differences

Item	Devices k050182	Predicate k023558
Methodology	Amperometric	Photometric
Measuring Range	150-350 mg/dL	100-400 mg/dL
Test Read Time	30 seconds	45 seconds
Sample Volume Application	Approximately 15 µL or 1 drop is added to the test spot	Approximately 135µL or 3 drops are added to the test spot
Test	Cholesterol only	Lipid Panel

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

1) General Principles of Software Validation; Final Guidance for Industry and FDA Staff, FDA, January 11, 1997.

2) IEEE Standard 1012-1986, IEEE Standard for Software Verification and Validation Plans, The institute of Electrical and Electronic Engineers, Inc. 1997.

3) Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Department of Health and Human Services, Food and Drug Administration, July 2000.

4) Quality Systems – Model for quality assurance in design, development, production, installation and servicing, ISO 9001:2000, International Organization for Standardization.

L. Test Principle:

The Test Principle used by this device is enzyme electrochemical sensor technology. Biomedix's biosensor uses a separate disposable dry reagent strip a for glucose and cholesterol determinations. When a drop of blood from the fingertip is applied to the half-circle test spot on the glucose test strip or the circular test spot on the cholesterol test strip, the reduction and oxidation reaction causes electron transfer at the electrode surfaces. Current is generated and detected by the Q.STEPS Biometer G/C Dual Monitoring System. The magnitude of the current generated is proportional to the analyte concentration in the blood.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. Precision/Reproducibility:

Glucose

The sponsor indicated glucose spiked venous whole blood was used to perform the Within-Run Precision Study. Commercially purchased venous blood was pooled together and spun down to separate the erythrocytes from plasma. The venous blood was then adjusted to 45 ± 3% hematocrit with the plasma. Five different concentrations of glucose spiked whole blood solutions were made by adding the concentrated glucose solution into the whole blood. These glucose spiked whole blood samples were used for the within-run precision study. Each sample was measured twice per day for 20 days. As shown in the table below, the values of C.V were between 2.7% and 8.0%

Within-run precision results with venous whole blood on Biometer G/C

Lot #	Glucose Concentration (mg/dL) measured by YSI	Total Number of Samples (N)	Within Run Mean by Biometer (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation %
1	50	20	60	2.5	4.3
	80	20	87	4.5	5.2
	120	20	110	8.5	7.8
	200	20	224	11.0	4.9
	400	20	353	16.5	4.7
2	50	20	49	3.1	6.3
	80	20	91	7.3	8.0
	120	20	124	9.6	7.8
	200	20	217	13.9	6.4
	400	20	372	10.3	2.8
3	50	20	65	2.8	4.9
	80	20	84	3.5	4.1
	120	20	125	3.1	2.6
	200	20	240	6.6	2.7
	400	20	432	16.8	4.2

The average within-run total variation coefficient with whole blood was between 3.75 and 5.86%.

Summary results of within-run precision with whole blood.

	Glucose Concentration (mg/dL) measured by YSI	Average Mean by Biometer G/C (mg/dL)	Average Standard Deviation by Biometer G/C (mg/dL)	Average Coefficient of Variation [<8%] %
All Three Lots	50	58	2.8	4.82
All Three Lots	80	87	5.1	5.86
All Three Lots	120	120	7.0	5.83
All Three Lots	200	227	10.5	4.63
All Three Lots	400	386	14.5	3.75

Cholesterol

The specimens used in the precision study were EDTA preserved whole blood samples that were obtained commercially. First, the whole blood samples were pooled together, spun down and plasma removed. The serum-base cholesterol stock solutions with the desired cholesterol level were then mixed with red blood cells to become a whole blood sample. The cholesterol-spiked blood was prepared at four target concentrations of 190, 200, 240, and 260 mg/dL. The venous blood was then adjusted to a final hematocrit of

45%. 15 µl of these blood samples were tested with the Q.STEPS Biometer G/C System, 20 times for each concentration. The values of within-run (average) total variation coefficient with whole blood were between 1.0 and 4.0%.

Whole blood precision

Lot#	Cholesterol Concentration by Cobas (mg/dL)	Total Number of Samples (n)	**Within-run** Mean by Biometer (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation %CV
Lot 1	190	20	185	6.11	3.30
	200	20	210	7.32	3.49
	240	20	238	7.94	3.33
	260	20	258	4.87	1.89
Lot 2	190	20	196	4.08	2.08
	200	20	203	6.43	3.17
	240	20	230	5.33	2.32
	260	20	263	5.30	2.01
Lot 3	190	20	181	7.35	4.05
	200	20	206	8.35	4.06
	240	20	226	8.71	3.85
	260	20	270	6.59	2.44

The sponsor determined the within run and day-to-day precision on the Q.STEPS System using Standard Cholesterol Solutions at 200mg/dL and 240 mg/dL. 25µl of the standard solution was applied to two test strips per concentration. Readings were taken twice per day for 10 consecutive days. Three different lots of test strips were tested. The within-run C.V. varied form 1.95% to 2.47%

Within-run precision results of Q.STEPS G/C with serum specimen

Lot#	Cholesterol Concentration	Total Number	Mean mg/dL	Within-run SD	% CV	Between run	Total precision SD	%CV
Lot 1	200	10	202	4.97	2.47	0	6.27	3.11
	240	10	243	5.34	2.19	0	6.00	2.47
Lot 2	200	10	202	4..49	2.22	0	5.91	2.93
	240	10	242	4.88	2.02	0	5.46	2.26
Lot 3	200	10	203	4.45	2.19	0	5.59	2.75
	240	10	243	4.71	1.95	0	5.13	2.12

Clinical Sites Precision Studies

Venous whole blood samples were collected from patients at three different clinical trial sites. 15µl of the whole blood was applied to each cholesterol test strip. Each blood sample was applied 20 times.

Precision data obtained from clinical sites

Location	Total number of samples (n)	Within-run Mean (mg/dL)	Within-run SD (mg/dL)	Within-run CV %
Site 1	20	192	5.91	3.08
	20	239	6.38	2.67
Site 2	20	209	6.02	2.89
	20	239	5.15	2.15
Site 3	20	206	6.35	3.09
	20	241	6.86	2.85

b. Linearity/assay reportable range:

Glucose

The sponsor pooled 980µl of venous blood and adjusted the hematocrit to 45% ± 3. The pooled sample was then spiked with a Glucose stock solution resulting in blood glucose concentrations of 25 mg/dL, 50 mg/dL, 100 mg/dL, 200 mg/dL 300 mg/dL, 400 mg/dL, 500 mg/dL, 550 mg/dL and 600 mg/dL. Each sample was then measured by the YSI STAT PLUS analyzer, as a reference, and then 10 µl of the sample was placed on the Q.STEPS Side Sensor Test Strip and Biometer G/C. Each concentration level of whole blood glucose spiked solution was applied to four test strips. The average reading was taken for the measurements.

Results

For each lot of test strips, the glucose concentration determined by the Q.STEPS Biometer G/C was plotted against the glucose concentration determined by the YSI 2300

Linearity studies of whole blood

Lot #	Tested Range	R^2	Slope	Intercept
Lot l	50-400 mg/dL	0.99	1.025	3.9
Lot 2	25-600 mg/dL	0.98	1.192	-13
Lot 3	25-600 mg/dL	0.99	1.033	-2.6

Cholesterol

The sponsor spiked 15 µl of venous blood with cholesterol stock solutions resulting in blood cholesterol concentrations of 150 mg/dL, 200 mg/dL, 240 mg/dL, 300 mg/dL and 350 mg/dL. The cholesterol concentration of each sample was first measured by the Cobas Mira PLUS, as a reference, and then 15µl of the sample was placed on the Q.STEPS Cholesterol Test Strip and the Biometer G/C. Each level of whole blood cholesterol spiked solution was applied to four test strips. The average readings were taken for the measurement of linear regression.

Results
For each lot of test strips, the Cholesterol concentration determined by the Q.STEPS Biometer was plotted against the Cholesterol concentration determined by the Cobas Mira PLUS.

Linearity studies of whole blood

Lot #	Tested Range	R^2	Slope	Intercept
Lot l	150-350 mg/dL	0.96	1.03	-6.47
Lot 2	150-350 mg/dL	0.99	1.01	-0.09
Lot 3	150-350 mg/dL	0.98	1.05	-15.76

c. Traceability (controls, calibrators, or method):

The traceability of the Glucose and Cholesterol calibrators and controls are verified against commercially available Standard Reference Material from the National Institute of Standards and Technology (formerly NBS).

1. Commercially available (serum based) Standard Cholesterol Solutions
2. "Current Status of Blood Cholesterol Measurement in Clinical Laboratories in the United States: A report from the Laboratory Standardization Panel of the National Cholesterol Education Program". Clin. Chem 34/1, 1998, 193-201.
3. "Recommendations for Improving Cholesterol Measurement: A report from the Laboratory Standardization Panel of the National Cholesterol Education Program". NIH Publication No. 90-2964, February 1990.

d. Detection limit:

Glucose 50 – 400 mg/dL

Cholesterol 150 – 350 mg/dL

e. Analytical specificity:

Glucose

According to the sponsor twenty-three commonly tested interferent substances were examined. No interference was observed in bilirubin, creatinine and citrate at physiological levels. Based on the tested concentrations, 4-acetamidophenol, ascorbic acid, dopamine, L-Dopa, Ibuprofen, methyldopa, and uric acid interfered with some glucose measurements.

Tested interference substances, concentrations, and their effects.

Substance	Physiological Therapeutic Levels (mg/dL)	Toxic (mg/dL)	Substance Tested Conc. (mg/dL)	Interference At Glucose 80 mg/dL	Interference At Glucose 200 mg/dL)	Effect of low gluc conc. (80mg/dL)	Effect of high gluc conc. (200 mg/dL)
4Acetamindophenol	1.0-2.0	15	2.0-6.0	No inter up to 2.0 mg/dL	No inter up to 4.0 mg/dL	▲	▲
Ascorbic Acid	0.8- 1.2	-	1.0-4.0	No inter up to 2.0 mg/dL	Inter at 1.0 mg/dL	▼	▼
Bilirubin	0.1-1.2	-	6.8-20	No inter up to 20 mg/dL	No inter up to 20 mg/dL	–	–
Cholesterol	<200	-	300	No inter	No inter	–	–
Citrate sodium salt	1.7-3.0	-	8.9-26.6	No inter	No inter	–	–
Creatinine	0.6-1.2	-	21.9-65.7	No inter	No inter	–	–
Dextrin	-	-	0.1-0.2	No inter	No inter	–	–
L-Dopa	0.02-0.03	-	0.23-6.9	No inter up to 2.3 mg/dL	No inter up to 2.3 mg/dL	▲	▲
Dopamine	0.4-1.6	-	0.02-2.6	No inter up to 0.7 mg/dL	No inter up to 0.52 mg/dL	▲	▲
EDTA	61	240	100-400	No inter	No inter	–	–
D-Galactose		-	22.1 – 66.2	No inter	No inter	–	–
Ibuprofen	0.5-4.2	-	27-81	No inter	No inter up to 54 mg/dL	–	▼
K3Fe(CN)6	0.07	2.86	0.2-0.5	No inter	No inter	–	–
Maltose	-	-	18-54	No inter	No inter	–	–
D-Mannose	5.0-7.5 mg/day	-	10-30	No inter	No inter	–	–
Mega8	-	-	0.2-0.5	No inter	No inter	–	–
Methyldopa	0.1-0.5	>1.0	1.2-3.5	No inter up to 2.0 mg/dL	No inter up to 1.0 mg/dL	▼	▼
Salicylic acid	15-30	>40	8.7-	No inter	No inter	▼	▼

Substance	Physiological Therapeutic Levels (mg/dL)	Toxic (mg/dL)	Substance Tested Conc. (mg/dL)	Interference At Glucose 80 mg/dL	Interference At Glucose 200 mg/dL)	Effect of low gluc conc. (80mg/dL)	Effect of high gluc conc. (200 mg/dL)
			26.1	up to 25 mg/dL	up to 50 mg/dL		
Tetracycline	0.4	-	1.8-5.4	No inter	No inter	—	—
Tolazamide	2.0-2.5	-	1.6-5.4	No inter	No inter	—	—
Triglyceride	<190	-	100-300	No inter	No inter	—	—
Uric Acid	M: 2.1-7.8 F: 2.0- 6.4	-	2.7-8.1	No inter up to 2.7 mg/dL	No inter up to 5.4 mg/dL	▲	▲
D-Xylose	-	-	15.3-45.9	No inter	No inter	—	—

Cholesterol

The sponsor tested ten common endogenous or exogenous substances for cholesterol meters. Hemoglobin was also tested due to the occurrence of hemolyzed specimens. The sponsor utilized a Student t test for statistical analysis. Paired differences were analyzed to determine statistically significant differences between 3 lots of cholesterol test strips. A p value less than .05 was considered to be statistically significant. The therapeutic and toxic concentrations of the interferents are listed in the below table.

Tested interference substances, concentrations, and their effects.

Substance	Physiological Therapeutic Levels (mg/dL)	Toxic (mg/dL)	Substance Tested Conc. (mg/dL)	Interference At Chol 200 mg/dL	Interference At Chol 240 mg/dL)	Effect of low chol conc. (200 mg/dL)	Effect of high chol conc. (240 mg/dL)
4Acetamindophenol	1.0-2.0	>15	1.5-6.0	No inter up to 3.0 mg/dL	No inter up to 3.0 mg/dL	▲	▲
Ascorbic Acid	0.8- 1.2	-	1.0-4.0	No inter up to 2.0 mg/dL	Inter at 1.0 mg/dL	▼	▼
Bilirubin	0.1-1.2	-	6.8-20	No inter up to 20 mg/dL	No inter up to 20 mg/dL	—	—
Dopamine	0.4-1.6	-	0.02-2.6	No inter up to 8.0 mg/dL	No inter up to 4.0	▼	▼
EDTA	61	240	100-	No inter	No inter	—	—

Substance	Physiological Therapeutic Levels (mg/dL)	Toxic (mg/dL)	Substance Tested Conc. (mg/dL)	Interference At Chol 200 mg/dL	Interference At Chol 240 mg/dL)	Effect of low chol conc. (200 mg/dL)	Effect of high chol conc. (240 mg/dL)
			400	up to 400 mg/dL	up to 400 mg/dL		
Hemoglobin	10 mg/dL	-	22.1 – 66.2	No inter up to 200 mg/dL	No inter up to 200 mg/dL	–	–
Ibuprofen	0.5-4.2	-	27-81	No inter up to 10 mg/dL	No inter up to 20 mg/dL	▲	▲
Methyldopa	0.1-0.5	>1.0	1.2-3.5	No inter up to 2.0 mg/dL	No inter up to 1.0 mg/dL	▼	▼
Salicylic acid	15-30	>40	8.7-26.1	No inter up to 25 mg/dL	No inter up to 50 mg/dL	▼	▼
Triglyceride	<190	-	475 – 1900	No inter up to 1900 mg/dL	No inter up to 1900 mg/dL	–	–
Uric Acid	M: 2.1-7.8 F: 2.0- 6.4	-	5.0-20.0	No inter up to 10.0 mg/dL	No inter up to 5.0 mg/dL	▼	▼

Hematocrit Study

Glucose

The sponsor obtained venous whole blood samples that were pooled, and then spun down to separate the red cells from the plasma. The plasma was adjusted to the desired target hematocrit concentration levels of approximately 20%, 25%, 30%, 40%, 45%, 50%, and 60%. Each hematocrit level had 5 target glucose concentrations (50 mg/dL, 80 mg/dL, 120 mg/dL, 200 mg/dL and 400 mg/dL), which were prepared by spiking with appropriate volumes of glucose stock solutions.

The sponsor's acceptance criteria for this study was determined to be hematocrit levels that exhibit glucose concentrations within ± 20% of that glucose reading of the same specimen at 45% hematocrit level.

Glucose Conc. (mg/dL)	Hematocrit Percent Levels							
	20%	25%	30%	35%	40%	50%	55%	60%
50	16.1	19.7	12.7	8.1	-0.7	-6.4	-19.7	-22.1
80	25.3	14.5	19.6	2.1	-2.2	-9.8	-7.3	-7.4
120	21.7	11.4	10.5	5.6	-3.7	-9.7	-10.2	-18.5
200	22.9	23.0	14.2	-1.3	-2.7	-1.4	-7.0	-17.7
400	10.0	-4.7	-3.0	4.7	-0.3	-7.2	-11.0	-18.2
	Hematocrit Percent Levels							
50	20.9	27.4	8.2	6.9	3.6	-2.5	-5.9	-10.0
80	8.5	3.8	3.1	2.2	-5.6	-8.0	1.3	-8.3
120	13.5	11.6	8.2	6.7	3.4	-2.0	-10.1	-15.9
200	11.3	15.3	11.1	7.2	1.5	-5.3	-14.4	-14.5
400	1.8	-11.7	4.0	7.8	6.3	-4.0	-5.7	-11.1

Cholesterol

The sponsor obtained venous whole blood samples that were pooled, and then spun down to separate the red cells from the plasma. The plasma was adjusted to the desired target hematocrit concentration levels of approximately 20%, 25%, 30%, 40%, 45%, 50%, and 60%. Each hematocrit level had 2 target cholesterol concentrations (200 and 240 mg/dL), which were prepared by spiking with appropriate volumes of cholesterol stock solutions. 15 µl of the adjusted whole blood sample was applied to the cholesterol test strips. The data is presented below.

Percent difference in hematocrit

Cholesterol Conc. (mg/dL)	Hematocrit Percent Levels							
	20%	25%	30%	35%	40%	50%	55%	60%
200	13.4	13.4	11.5	8.7	6.1	5.1	2.3	-12.4
240	22.1	22.1	13.7	7.7	5.6	-2.6	3.9	-11.6
	Hematocrit Percent Levels							
200	20.5	10.5	15.0	5.0	1.5	-5.0	3.0	-10.3
240	10.5	10.5	10.0	5.0	2.9	-2.9	-6.7	-10.0

f. Assay cut-off:
Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Glucose

Method comparison studies were performed at three different clinical sites. The correlation studies were made between the Biometer (k050182) new device, One Touch (k031472) predicate device, and the YSI (reference method) utilizing finger stick whole blood samples. The sponsor indicated that each home user performed their own fingerstick and performed the test on the Q.STEPS Biometer G/C. The measurement was also read by the professionals.

The professionals then performed another fingerstick on the same home user and performed a glucose test on the same device with the same lot of test strips. All of the results were masked from each other. The professional then tested the same user with the One Touch and YSI methods. The comparison results are presented the table below. The results are expressed as the mean absolute bias and regression analysis.

Comparison of fingertip whole blood results from three different clinical sites.

Site	Test Strip Lot #	Results Comparisons	Total Patients Tested	Mean of Absolute Bias (%)	Regression Analysis Slope	Regression Analysis Intercept	Regression Analysis Coefficient Variation (r)
Physician Office (Site 1)	Lot 1	Home User vs. YSI	171	8.0	1.01	3.12	0.96
		Home User vs. Professional	171	6.6	1.00	-0.98	0.96
		Professional vs. Predicate Device (One Touch)	175	9.3	0.91	15.03	0.95
		Professional vs. YSI	163	8.4	0.97	8.15	0.96
Physician Office (Site 2)	Lot 2	Home User vs. YSI	126	9.5	1.00	-1.59	0.93
		Home User vs. Professional	126	7.8	1.00	-1.01	0.95
		Professional vs. Predicate Device (One Touch)	130	8.0	0.98	5.8	0.92
		Professional vs. YSI	126	7.7	0.97	2.1	0.95
Physician Office (Site 3)	Lot 3	Home User vs. YSI	40	7.7	0.96	4.07	0.96
		Home User vs. Professional	40	5.4	1.00	-1.44	0.96
		Professional vs. Predicate Device (One Touch)	40	8.7	0.96	10.12	0.94
		Professional vs. YSI	40	6.4	0.96	6.39	0.95

Cholesterol

Method comparison studies were compared with the Abel-Kendall reference method performed in a CDC- certified Cholesterol Reference Method Network Laboratory (CRMLN). The Abell-Kendall method is performed with serum only. External studies were also done at three different clinical sites by Lay-users. A total of 456 patients from the three different sites participated in the clinical trial.

The lay-users performed their fingerstick and performed the cholesterol test on the Q.STEPS Biometer G/C System and the results were recorded by the lay-user and professional. The professional also performed a finger stick cholesterol test on the same lay-user using the same Biometer G/C System with the same lot of test strips. The professional from each site also drew a tube of venous blood from 14-16 lay-users in order to send the serum to CRMLN for comparison. Comparison results are presented in the table below.

Comparison Results from Three Different Clinical Sites

Site	Test Strip Lot #	Results Comparisons	Total Patients Tested	Regression Analysis Slope	Regression Analysis Intercept	Regression Analysis Coefficient Variation (r)
Physician Office (Site 1)	Lot 1	Home User Performed / Read vs. Professional Performed/ Read	195	0.94	13.57	0.93
		Home User Performed/ Read vs. Home User Performed/ Read	195	1.00	0.00	1.00
		Home User Performed/ Read vs. CRMLN	36	0.93	15.10	0.92
		Professional Performed/ Read vs. CRMLN	36	0.87	26.15	0.91
Physician Office (Site 2)	Lot 2	Home User Performed / Read vs. Professional Performed/ Read	146	1.00	-1.84	0.95
		Home User Performed/ Read vs. Home User Performed/ Read	146	1.00	0.00	1.00
		Home User Performed/ Read vs. CRMLN	23	0.96	11.15	0.98
		Professional Performed/ Read vs. CRMLN	22	0.93	17.51	0.97
Physician Office (Site 3)	Lot 3	Home User Performed / Read vs. Professional Performed/ Read	115	0.91	16.59	0.91
		Home User Performed/ Read vs. Home User Performed/ Read	115	1.00	0.00	1.00
		Home User Performed/ Read vs. CRMLN	28	0.94	16.55	0.98
		Professional Performed/ Read vs. CRMLN	28	0.95	19.09	0.98

The bias between the CRMLN and Q.STEPS Biometer G/C Dual Monitoring System at the medical decision points of 200 mg/dL and 240 mg/dL, about 4.65% were positively misclassified and 2.33% were negatively classified.

b. Matrix comparison:

Not Applicable

3. Clinical studies:

a. Clinical sensitivity:

See above

b. Clinical specificity:
See above

c. Other clinical supportive data (when a and b are not applicable):
See Comparison Studies referenced above.

4. Clinical cut-off:
Not Applicable

5. Expected values/Reference range:

Glucose
Patient glucose ranges for non-diabetic, non-pregnant adults:

Glucose fasting	70 mg/dL – 110 mg/dL 3.9 mmol/L – 6.1 mmol/L
1 hour after meal[1]	< 160 mg/dL (<8.9 mmol/L)

1. Krall, LP and Deaser, RS: Joslin Diabetes Manual. Lea and Febiger. (1989) 138.

Cholesterol
According to NCEP classification, patient cholesterol ranges for non-diabetic, non-pregnant adults[1]:

Desirable blood cholesterol	<200 mg/dL (<5.17 mmol/L)
Borderline-high blood cholesterol	200 mg/dL -239 mg/dL (5.17 mmol/L – 6.18 mmol/L)
High blood cholesterol	>240 mg/dL (>6.21 mmol/L)

1. National Cholesterol Education Program. Summary of the Second report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adults Treatment Panel II). JAMA 1993; 269:3015-23 Davidsohn & Henry, Clinical Diagnosis by Laboratory Methods. Todd-Sandford.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

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