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

A. 510(k) Number:

k123007

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose from the finger, palm and forearm

D. Type of Test:

Quantitative amperometric assay, glucose oxidase

E. Applicant:

MiCoBioMed Co., Ltd.

F. Proprietary and Established Names:

Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System

Veri-Q plus MGD-1001 Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR: 862.1345, Glucose Test System

21 CFR 862.1660, Quality control material (assayed and unassayed)

2. Classification:

Class II

Class I, reserved

3. Product code:

NBW, System, Test, Blood Glucose, Over the Counter
CGA, Glucose Oxidase, Glucose
JJX, Single (specified) analyte controls (assayed and unassayed)

4. Panel:

75 (clinical chemistry)

H. Intended Use:

1. Intended use(s):

See Indications for Use below

2. Indication(s) for use:

The Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System:

The Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, or forearm. The Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. The Veri-Q self-testing MGD-1001 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 Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady–state times (when glucose is not changing rapidly).

The Veri-Q self-testing MGS-01 test strips are for use with the Veri-Q self-testing MGD-1001 meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, or forearm.

The Veri-Q self-testing Glucose Control Solutions are for use with the Veri-Q self-testing MGD-1001 meter and Veri-Q self-testing MGS-01 test strips to check that the meter and test strips are working together properly and providing accurate results.

The Veri-Q plus MGD-1001 Blood Glucose Monitoring System:

The Veri-Q plus MGD-1001 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose (sugar) in fresh capillary whole blood drawn from fingertips, palm, or forearm. The Veri-Q plus MGD-1001 Blood Glucose Monitoring System is intended for testing outside the body (in

vitro diagnostic use). The Veri-Q plus MGD-1001 Blood Glucose Monitoring System is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. This system is only used with single-use, auto-disabling lancing devices. The Veri-Q plus MGD-1001 Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady–state times (when glucose is not changing rapidly).

The Veri-Q plus MGS-01 test strips are for use with the Veri-Q plus MGD-1001 meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, or forearm.

The Veri-Q plus Glucose Control Solutions are for use with the Veri-Q plus MGD-1001 meter and Veri-Q plus MGS-01 test strips to check that the meter and test strips are working together properly and providing accurate results.

3. Special conditions for use statement(s):

Veri-Q MGD-1001 Blood Glucose Monitoring System is for over-the-counter use
Not for neonatal use
Not for screening or diagnosis of diabetes mellitus
Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients
Veri-Q MGD-1001 Blood Glucose Monitoring System is for single-patient use only
Veri-Q plus MGD-1001 Blood Glucose Monitoring System is for multiple user use
Alternative site testing (AST) testing should only be done during steady-state times (when glucose is not changing rapidly).
AST should not be used to calibrate continuous glucose monitors (CGMs).
AST should not be used for insulin dose calculations.

4. Special instrument requirements:
The Veri-Q self-testing MGD-1001 Blood Glucose Monitoring System is intended for use with Veri-Q MGS-01 and MGS-01B test strips and Veri-Q Glucose Control Solutions

The Veri-Q plus MGD-1001 Blood Glucose Monitoring System is intended for use with Veri-Q plus MGS-01 and MGS-01B test strips and The Veri-Q plus Glucose Control Solutions

I. Device Description:

Veri-Q self-testing MGD-1001 and Veri-Q plus MGD-1001 Blood Glucose Monitoring Systems consist of the Veri-Q self-testing MGD-1001 and Veri-Q plus MGD-1001 meters, Veri-Q self-testing MGS-01 and Veri-Q plus MGS-01 test strips (sold separately), Veri-Q control solutions (Levels 1, 2 and 3; sold separately), lancing device (for use with the single-patient use system only), lancets (sold separately), user manual, quick reference guide, and carrying case.

Each test strip contains: Glucose oxidase Aspergillus niger); Potassium Ferricyanide (-

and other non-reactive ingredients.

Each box of Veri-Q Blood Glucose Control Solution contains one vial (4 mL) of each of the 3 buffered aqueous solutions containing D-glucose: Level 1 (30-50 mg/dL), Level 2 (94-144 mg/dL) and Level 3 (280-420 mg/dL).

J. Substantial Equivalence Information:

1. Predicate device name(s):

CareSensN Blood Glucose Monitoring System, by i-SENS, Inc.

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

k083468

3. Comparison with predicate:

Similarities and Differences		
Item	Candidate Device	Predicate Device (k083468)
Indications for Use/Intended Use	It is intended to be used for quantitative measurement of glucose in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Enzyme	Glucose Oxidase	Same
Detection Method	Electrochemical Biosensor	Same
Measurement range	20-600 mg/dL	Same
Measuring time	5 sec	Same
Sample volume	0.5 μL	Same
Sample Site	Fingertip, palm and forearm	Fingertip, forearm, palm, thigh, and calf
Hematocrit range	20-60%	Same
Meter memory	300 test results	250 test results
Control Solution	3 Levels	2 Levels

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

- ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
- CLSI EP6-A, Evaluation of the Linearity Quantitative Analytical Method; Approved Guideline.
- CLSI EP7-A2, Interference Testing in Clinical Chemistry; Approved Guideline.

- EN 61326-1: 2006; Electrical equipment for measurement, control and laboratory use-EMC requirements-Part1: General requirements.
- EN 61326-2-6: 2006; Electrical equipment for measurement, control and laboratory use-EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment.
- IEC 61010-2-101:2002; Safety Requirements for electrical equipment for measurement, control and laboratory use Part2-101: Particular requirements for In Vitro Diagnostic (IVD) Medical Equipment.
- IEC 60068-2-1: 2007; Environmental testing – Part 2-1; Test-Test A: Cold
- IEC 60068-2-2: 1993; Basic environmental testing procedures – Part 2: Test-Test B: Dry
- IEC 60068-2-64: 2008; Environmental testing – Part 2: Test methods-Test Fh: Vibration, broad-band random (digital control) and guidance.
- IEC 60068-2-78: 2001; Environmental testing – Part 2-78; Tests-Test Cab: Damp heat, steady state.
- IEC 61010-1:2001; Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements.
- CISPR 11:2003; Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment

L. Test Principle:

Glucose in the blood sample reacts with glucose oxidase (GOD) on the test strip and a DC Electrical current is produced. This current is measured by the Veri-Q meter and displayed as the Blood glucose result. The strength of these currents changes with the amount of glucose in the blood sample. The Veri-Q meter automatically interprets this reaction.

M. Performance Characteristics (if/when applicable):

The Veri-Q self-testing MGD-1001 and Veri-Q plus MGD-1001 meters are the same meters that use the same test strip; however the systems, meters, and test strips have separate names due to their different indications for use. Therefore, only one set of performance data is presented below.

1. Analytical performance:

   a. *Precision/Reproducibility:*

      The Veri-Q MGD -1001 BGM system was evaluated for repeatability using spiked or glycolyzed venous whole blood (hematocrit level 30%-50%) at the following glucose concentrations. (30 to 50, 51 to 110, 111 to 150, 151 to 250, and 251 to 400 mg/dL).

      Each concentration was tested 10 times each on 10 meters, using 500 test strips from 3 test strip lots. Results are summarized below:

	Within day precision			
Strip Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Lot 1	100	45	1.8	3.93
	100	89.2	2.7	3.07
	100	120.9	3.4	2.84
	100	229.2	6.8	2.95
	100	318.2	8.7	2.72
Lot 2	100	44.7	1.8	4.04
	100	88	3.3	3.79
	100	121.2	4.2	3.44
	100	231.6	8..3	3.6
	100	320	9.2	2.88
Lot 3	100	45.3	1.9	4.15
	100	88.5	3.7	4.2
	100	120.9	4.4	3.6
	100	233.5	8.9	3.82
	100	315.9	7.8	2.48

Intermediate precision was evaluating using three glucose control solutions (Level 1, Level 2 and Level 3). Each concentration was tested in replicates of 10, with three test strip lots and 10 Verio-Q MGD-1001 meters for a total of 300 measurements per glucose level. Results are summarized below:

	Intermediate precision (control materials)				
Strip Lot	Concentration (mg/dL) of glucose	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Lot 1	40.1	100	40.4	1.8	4.41
	115.1	100	114.4	3.9	3.44
	337.7	100	338.8	8.0	2.37
Lot 2	40.1	100	39.0	1.9	4.79
	115.1	100	113.1	3.9	3.48
	337.7	100	337.5	8.0	2.36
Lot 3	40.1	100	39.4	1.8	4.52
	115.1	100	113.4	3.9	3.47
	337.7	100	337.8	8.0	2.37

b. Linearity/assay reportable range:

The sponsor performed linearity studies using adjusted venous blood samples with 11 different glucose concentrations ranging from18.1 to 602.5 mg/dL (18.1, 27.8, 47.1, 56.9, 66.8, 85.5, 90.9, 164.5, 237.5, 310.5, 382.5, 455.0, 530.0 and 602.5 mg/dL) for the Veri-Q MGD -1001 BGM system. These measurements were made using the reference method (YSI 2300 STAT Plus).
Each sample was tested in replicates of 5 on the Veri-Q MGD-2001 using 3 test strip lots. The values from the Veri-Q MGD-1001 meter were compared with those obtained from the reference method (YSI). The resulting data was compared and the linear regression analyses were as follows:

Strip Lot	Linear Regressions	slope	Y-Intercept	R2
Lot. #1	y=0.9985x+0.1285	0.9985	0.1285	1.000
Lot. #2	y=0.9988x-0.0066	0.9988	-0.0066	1.000
Lot. #3	y=0.9999x+0.0213	0.9999	0.0213	1.000
Combined	y=0.9991x+0.0477	0.9991	0.0477	1.000

The MGD-1001 meters display “Low” with glucose values below 20 mg/dL, “Hi” with glucose values over 600 mg/dL.
The results of the study support the sponsor’s claimed glucose measurement range of 20 to 600 mg/dL.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
The sponsor states that the Veri-Q MGD-1001 system is traceable to the NIST SRM 917b glucose reference material. A method comparison was performed using the candidate device and YSI as the reference method (see Section 2.a.).

Control Solution Value Assignment and Stability:
Value assignment: Three levels of aqueous control solutions are available for use with the Veri-Q MGD 1001 test system: Level 1 (30-50 mg/dL), Level 2 (94-144 mg/dL) and Level 3 (280-420 mg/dL). Value assignment for use of the control solutions with the Veri Q MGD-1001 blood glucose test strips is based on replicate measurements using the YSI 2300. . The values for each of the control solutions are assigned by repeat analysis using the Veri-Q MGD-1001 meter and MGD-01 each test strips and the mean used to establish the ranges for each control solution level which are provided on the test strip vial label.

Control Solution Stability: Stability was assessed using real-time and accelerated testing for each control solution level (Level 1, 2 and 3). Protocols and acceptance criteria were reviewed and found to be acceptable to support the shelf life stability claim of 24months and an open-vial stability claim of 3 months when stored at the recommended storage temperatures of 46°F to 86°F (8-30°C). Labeling instructs the user not to refrigerate the solutions.

Test Strip Stability: The sponsor provided a real-time and accelerated testing protocol and acceptance criteria to verify the closed- (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) of 20 months and open-vial stability of 3 months when stored at 46-86°Fand 10-90% relative humidity. The labeling instructs the users not to refrigerate or freeze the test strips.

d. Detection limit:

The reportable range is 20 to 600 mg/dL based on linearity/reportable range studies above in M.1.b.

e. Analytical specificity:

To assess potential interference the sponsor used venous whole blood samples adjusted to three glucose concentration intervals of 30 to 50 mg/dL and 100 to 120 mg/dL and 480-520 mg/dL. Each of these samples was divided into a test pool and a control pool and each of the potential endogenous and exogenous interfering substances was added to the test pool. Each substance was tested at a minimum of two concentrations, normal/therapeutic and high/toxic concentrations. Each sample was analyzed in replicates of 5. The % difference between the test sample and the control sample was calculated. The sponsor defines no significant interference as $\leq \pm 10$ mg/dL difference relative to the control sample with glucose concentrations <75 mg/dL and $\leq \pm 10$ % with glucose concentrations ≥ 75 mg/dL. Results are presented in the table below:

Potential Interfering Substance	Concentration at which no significant interference is observed (mg/dL)	Potential Interfering Substance	Concentration at which no significant interference is observed (mg/dL)
Acetaminophen	7	Maltitol	1000
Ascorbic Acid	6	Maltose	1000
Bilirubin (unconjugated)	20	Mannitol	1000
Caffeine	10	Mannose	1000
Cholesterol	500	Methyl-Dopa	1.5
Citric Acid	30	Pseudoephedrine	10
Creatinine	10	Salicylic acid	50
Dopamine	1.5	Sodium Chloride	200 mmol/L
Ephedrine	60	Sorbitol	1000
Galactose	1000	Tetracycline	4
Gentisic acid	2.5	Tolazamide	12
Hemoglobin	20 g/dL	Tolbutamide	50
Ibuprofen	50	Triglycerides	1500
Isomalt	1000	Urea	600
Lactitol	1000	Uric acid	10
Lactose	1000	Xylitol	1000
L-Dopa	1.0	Xylose	1000

The sponsor has the following limitations in their labeling:

Acetaminophen at concentration of 7 mg/dL and higher interferes with glucose concentration reading; Dopamine at concentration of 1.5 mg/dL and higher increases glucose concentration reading; L-dopa at concentration of 1.0 mg/dL and higher increases glucose concentration reading; Methyldopa at concentration of 1.5 mg/dL and increases glucose concentration reading; Uric acid at concentration of 10 mg/dL and higher increases glucose concentration reading

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

To assess system accuracy, results from the Veri-Q MGD-1001 Blood Glucose Monitoring System were compared to a reference method, YSI 2300 STAT Plus. Trained healthcare professionals obtained fingerstick capillary samples from 200 participants with glucose concentrations ranging from 48-429 mg/dL glucose obtained using the reference method. The results of the Veri-Q MGD system relative to reference are summarized in the tables below:

Method comparison study results for glucose concentration <75 mg/dL

Meter	Within ±5	Within ±10	Within ±15
#1	36/39 (92.3%)	39/39 (100%)	39/39 (100%)
# 2	33/39 (84.6%)	39/39 (100%)	39/39 (100%)

Method comparison study results for glucose concentration ≥ 75 mg/dL

Meter	Within ±5%	Within ±10%	Within ±15%	Within ±20%
# 1	150/161	161/161 (100%)	161/161	161/161 (100%)
# 2	145/161	161/161 (100%)	161/161	161/161 (100%)

Regressions between MGD-1001 Blood Glucose Monitoring System results and the YSI method for the fingerstick samples:

Meter Lot #	Linear Regressions	95% CI Slope	95%CI	R^2	N
#1	Y=1.0034X – 0.3911	1.0034	-0.3911	0.9961	200
# 2	Y=1.006X – 0.1895	1.006	-0.1895	0.9954	200

1

To assess the performance of alternative site testing using the Veri-Q- MGD -1001 Blood Glucose Monitoring System were compared to a reference method, YSI 2300. Capillary samples with glucose concentrations ranging from 53 to 443 mg/dL were obtained from 100 participants by a trained technician using three test strip lots. Results were analyzed by comparing blood glucose results from the Veri-Q MGD-1001 meter against the YSI reference. The results are summarized in the tables below:

For glucose concentration <75 mg/dL

		Within ±5	Within ±10	Within ±15
Professionals	Palm vs. YSI	11/13 (84.6%)	13/13 (100%)	13/13 (100%)
	Forearm vs. YSI	11/13 (84.6%)	13/13 (100%)	13/13 (100%)

For glucose concentration ≥ 75 mg/dL

		Within ±5%	Within	Within	Within
Professionals	Palm vs. YSI	76/87 (87.4%)	87/87 (100%)	87/87 (100%)	87/87 (100%)
	Forearm vs. YSI	79/87 (90.8%)	86/87 (98.9%)	87/87 (100%)	87/87 (100%)

Regression analysis results summarized

Professionals	Palm vs YSI	Y = 1.0109X – 1.732	0.9969	53 to 443
	Forearm vs YSI	Y = 1.0079X – 0.8815	0.9964	53 to 443

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 Veri-Q MGD-1001 Blood Glucose Monitoring System in the hands of the intended users the sponsor performed a study with 152 lay user participants. Following the user's self-test, healthcare professionals obtained a separate sample for the reference measurement (YSI). Results were analyzed by comparing fingerstick blood glucose results from the Veri-Q MGD-1001 system obtained by the lay user against YSI. The samples ranged from 61 to 427 mg/dL as measured by the reference method. The results of the Veri-Q MGD-1001 system relative to reference are summarized in the tables below:

Lay user results for glucose concentration <75 mg/dL

	Within ±5	Within ±10	Within ±15
Lay user vs. YSI	1/4 (25%)	2/4 (50%)	4/4 (100%)

Lay user results for glucose concentration ≥ 75 mg/dL

	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Lay user vs. YSI	118/148	144/148	148/148	148/148 (100%)

Regression analysis results are summarized below:

	Linear regression	R^2	N	Sample Range
Lay user vs. YSI	Y = 0.9875X +	0.994	152	61 to 427

Alternative Site Testing Study:

To assess the performance of alternative site testing using the Veri-Q Blood Glucose Monitoring System in the hands of the intended users the sponsor performed a study with 100 lay user participants, who collected 100 each of palm and forearm samples. . Results were analyzed by comparing blood glucose results from the Veri-Q meter obtained by the lay user against the YSI 2300 reference value obtained by a trained technician. The samples ranged from 53 to 443 mg/dL as measured by YSI. The results are summarized in the tables below:

System accuracy results for glucose concentration <75 mg/dL

		Within ±5	Within ±10	Within ±15
Lay users	Palm vs. YSI	11/13 (84.6%)	13/13 (100%)	13/13 (100%)
	Forearm vs. YSI	11/13 (84.6%)	13/13 (100%)	13/13 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

		Within ±5%	Within	Within	Within
Lay users	Palm vs. YSI	78/87 (89.7%)	87/87 (100%)	87/87 (100%)	87/87 (100%)
	Forearm vs. YSI	76/87 (87.4%)	86/87 (98.9%)	87/87 (100%)	87/87 (100%)

Regression analysis results summarized

		Linear regression	R^2	YSI value
Lay-users	Palm vs YSI	Y = 0.9955X + 0.0794	0.9959	53 to 443
	Forearm vs YSI	Y = 1.0049X – 1.1384	0.9921	53 to 443

4. Clinical cut-off:
   Not Applicable

5. Expected values/Reference range:

Time of day	People without diabetes
Fasting and before meals	<100 mg/dL
1-2 hours after meals	<140 mg/dL

American Diabetes Association: *Diabetes Care Vol* 36 (Supp. 1) January 2013, p S1-S100.

Instrument Name:

Veri-Q self-testing MGD-1001 Blood Glucose Meter
Veri-Q plus MGD-1001 Blood Glucose Meter

System Description:

1. Modes of Operation:

   Each test strip is single use and must be replaced with a new strip for additional readings.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?:
   Yes _____ or No __X__.

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?:
   Yes _____ or No __X__.

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes __X__ or No _____.

   The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

3. Specimen Identification:

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

4. Specimen Sampling and Handling:

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

5. Calibration:
   The system is designed to be non-coding. The test strips are coded a test strip lot-specific code. When the test strip is inserted into the meter it provides the appropriate calibration code information to the meter, therefore, the user is not required to enter any coding information or verify the coding.

6. Quality Control:
   Three levels of aqueous glucose control solutions are available with this system (Level 1, Level 2, and Level 3). Control solution Level 2 is provided with the kit. The control solution readings are not included in the average of the patient results when the 'M' or 'C' buttons are pushed after the measurement.
   Recommendations on when to test the control materials are provided in the labeling. An acceptable range for each control level is printed on the test strip vial label.

P. Other Supportive Device and Instrument Information:

1) Hematocrit study:
   The effect of different hematocrit levels was evaluated using venous whole blood samples with hematocrit levels of 20, 30, 40, 50, and 60% spiked with glucose to achieve target concentrations of 42, 85, 127, 237, and 360 mg/dL. Three test strip lots were evaluated and 10 meters. Each sample was tested in replicates of 21 for each hematocrit level and glucose level tested. The % bias of the Veri-Q MGD meter results relative to YSI was demonstrated adequate performance to support the claimed hematocrit range of 20 – 60%.

2) Altitude study:
To evaluate the effects of altitude on the Veri-Q MGD Blood Glucose Monitoring System a study was performed to simulate pressure and oxygen changes from altitude differences. Altered (spiked and glycolysed) venous blood samples from three donors were spiked to 3 glucose concentrations (63, 194 and 437 mg/dL). The blood samples were tested using 3 test strip lots and 5 meters at the simulated altitude and the results compared to those obtained with the reference method (YSI). The results demonstrate acceptable bias to the reference to support the claims in the labeling that altitudes up to 10,000 feet have no significant effect on blood glucose measurements from the Veri-Q MGD Blood Glucose Monitoring System.

3) Temperature and humidity studies:
The sponsor performed temperature and humidity studies using venous blood samples at target glucose concentrations of 42, 123, and 351 mg/dL to evaluate temperatures ranging from 50-104°F and relative humidity from 10-90%. Four combinations of the claimed temperature and humidity operating conditions were evaluated (low temperature/low humidity, low temperature/high humidity, high temperature/low humidity, and high temperature/high humidity). Meter results were compared to the reference method. The results support the claimed range of operating conditions: 50-104°F and 10-90% relative humidity.

4) Sample volume study:
The sponsor performed a sample volume study to support the claimed minimum sample volume requirement for the Veri-Q MGD-2001 system using blood samples of 0.3 μL, 0.5 μL, 0.8 μL, 1.0 μL, and 1.5 μL at five glucose concentrations (45, 83, 135, 272, 452 mg/dL according to the reference method). The system displays an error code (Er 3) when insufficient sample is detected. Results support the claimed minimum sample volume of 0.5 μL.

5) EMC and electrical safety testing was conducted in accordance to EN 61326- 1, EN 61326-2-6, IEC 60068-2-1, IEC 60068-2-2, IEC 60068-2-78, IEC 61010-1, IEC 60068-2-64, and IEC 60601-2-101 and the certification was provided.

6) Readability: Flesch-Kincaid readability assessment was conducted and the results demonstrated that both User Manual versions, inserts for both test strip versions and the control solution package insert were written at or below the 8th grade reading level.

7) Infection Control Studies: The device is intended for single- and multiple-patient use. CaviWipesXL (EPA registration #46781-8) was validated demonstrating complete inactivation of live virus for use with the meter and lancing device. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter after 10,950 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) and the lancing device after 1,950 cycles to simulate 3 years of device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection

procedures.

8) Customer Care Service Center is available 9 am to 5 pm CST, Monday – Friday by calling 855-241-0148

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.