

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

A. 510(k) Number:

k123016

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose from finger, palm and forearm

D. Type of Test:

Quantitative amperometric assay, glucose oxidase

E. Applicant:

MiCoBioMed Col, Ltd.

F. Proprietary and Established Names:

Veri-Q self-testing MGD-2001 Blood Glucose Monitoring System

Veri-Q plus MGD-2001 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:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indications(s) for use:

The Veri-Q self-testing MGD-2001 Blood Glucose Monitoring System:

The Veri-Q self-testing MGD-2001 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-2001 Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. The Veri-Q self-testing MGD-2001 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-2001 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-2001 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-2001 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-2001 Blood Glucose Monitoring Systems:

The Veri-Q plus MGD-2001 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-2001 Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use). The Veri-Q plus MGD-2001 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-2001 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-2001 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-2001 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):

For in vitro diagnostic use only

The single-patient use system is for single-patient use only and should not be shared

The multiple-patient use system should only be used with single-use, auto-disabling lancing devices

Not for neonatal use

Do not use for diagnosis of or screening for diabetes mellitus

Not for use on critically ill patients, patients who are dehydrated, hypotensive or in shock or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis

Alternative site testing (AST) should only be performed during periods of steady-state blood glucose conditions (when glucose is not changing rapidly).

Results from AST should not be used to calibrate continuous glucose monitors (CGMs).

Results from AST should not be used in insulin dose calculations.

4. Special instrument requirements:

The Veri-Q self-testing MGD-2001 meter

The Veri-Q plus MGD-2001 meter

I. Device Description:

Veri-Q self-testing MGD-2001 and Veri-Q plus MGD-2001 Blood Glucose Monitoring Systems consist of the Veri-Q self-testing MGD-2001 and Veri-Q plus MGD-2001 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).

I. Substantial Equivalence Information:

1. Predicate device name(s):

i-SENS Inc.; CareSens N Blood Glucose Monitoring System

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

k083468

3. Comparison with predicate:

Similarities and Differences		
Item	Candidate Device Veri-Q self-testing/plus MGD-2001 BGMS	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	Same

Similarities and Differences		
Item	Candidate Device Veri-Q self-testing/plus MGD-2001 BGMS	Predicate Device (k083468)
	diabetes control in people with diabetes.	
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:

The Veri-Q and Veri-Q plus MGD-2001 Blood Glucose Monitoring Systems are based on electrochemical biosensor technology and the principle of capillary action. The systems quantitatively measure blood glucose levels using glucose oxidase enzyme chemistry. The electrons generated during this reaction are transferred from the blood to the electrodes. The magnitude of the resultant current is proportional to the concentration of glucose in the specimen and the signal is converted into a readout displayed on the meter.

M. Performance Characteristics (if/when applicable):

The Veri-Q self-testing MGD-2001 and Veri-Q plus MGD-2001 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 sponsor performed repeatability studies using venous whole blood samples spiked or glycolized to achieve five different glucose concentrations (30 to 50, 51 to 110, 111 to 150, 151 to 250, and 251 to 400 mg/dL). Each glucose level was analyzed in replicates of 10, with 3 test strip lots and 10 meters, for a total of 300 tests per each glucose level, for each meter. Results are summarized below:

Glucose Level	30-50 (mg/dL)			50-110 (mg/dL)			110-150 (mg/dL)		
	1	2	3	1	2	3	1	2	3
Test Strip Lot									
Mean (mg/dL)	36.6	36.7	37.3	97.1	96.0	96.5	128.9	129.2	128.9
SD	1.5	1.8	1.9	2.9	3.3	3.7	3.4	4.2	4.4
CV%	4.1	4.9	5.1	3.0	3.4	3.8	2.6	3.3	3.4
n	100	100	100	100	100	100	100	100	100

Glucose Level	150-250 (mg/dL)			250-400 (mg/dL)		
	1	2	3	1	2	3
Test Strip Lot						
Mean (mg/dL)	236.8	239.6	241.5	326.3	326.3	323.9
SD	7.1	8.3	8.9	8.6	9.2	7.8
CV%	3.0	3.5	3.7	2.6	2.8	2.4
n	100	100	100	100	100	100

Intermediate precision was evaluated using three glucose control solutions (Level 1, Level 2, and Level 3). Each sample was measured in replicates of 10, with three

test strip lots and 10 Veri-Q MGD-2001 meters for 10 days, for a total of 300 measurements per glucose level. Results are summarized below:

Glucose Level	Level 1			Level 2			Level 3		
Test Strip Lot	1	2	3	1	2	3	1	2	3
Mean (mg/dL)	37.9	39.5	40.3	114.2	113.4	113.8	344.0	342.9	342.7
SD	4.4	3.2	2.7	3.9	4.1	4.4	11.3	10.6	10.9
CV%	11.6	8.1	6.7	3.4	3.6	3.9	3.3	3.1	3.2
n	100	100	100	100	100	100	100	100	100

b. Linearity/assay reportable range:

Linearity was evaluated using 12 venous blood samples ranging in glucose concentrations from 19.9 to 601.5 mg/dL (19.9, 29.5, 45.2, 54.2, 66.0, 84.3, 92.5, 154.8, 244.9, 325.0, 397.2, 465.6, 569.5, 601.5 mg/dL) as measured by 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-2001 meter were compared with those obtained from the reference method (YSI). The results from regression analysis are summarized below:

$$\text{Lot \#1: } y=1.0064x-0.753; R^2 = 0.999$$

$$\text{Lot \#2: } y=1.009 x-1.277; R^2 = 0.999$$

$$\text{Lot \#3: } y=1.0035x-0.8047; R^2 = 0.999$$

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-2001 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-2001 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-2001 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-2001 meter and Veri Q MGD-01 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 24 months 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°F and 10-90% relative humidity. The labeling instructs the users not to refrigerate or freeze the test strips.

d. Detection limit:

The reportable range for the Veri-Q MGD-2001 Blood Glucose Monitoring System is 20 to 600 mg/dL. This range was verified by the linearity study (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

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)
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-2001 Blood Glucose Monitoring System were compared to a reference method, YSI 2300 STAT Plus. Fingerstick capillary samples were obtained from 200 participants with glucose concentrations ranging from 48-426 mg/dL glucose obtained using the reference method. The results of the Veri-Q MGD-2001 system relative to reference are summarized in the tables below:

For glucose concentrations <75 mg/dL

Meter lot	within \pm 5 mg/dL	within \pm 10 mg/dL	within \pm 15 mg/dL
#1	36/39 (92.3%)	39/39 (100%)	39/39 (100%)
#2	36/39 (92.3%)	39/39 (100%)	39/39 (100%)

For glucose concentrations \geq 75 mg/dL

Meter lot	within \pm 5 %	within \pm 10 %	within \pm 15 %	within \pm 20 %
#1	154/161 (95.7%)	161/161 (100%)	161/161 (100%)	161/161 (100%)
#2	149/161 (92.5%)	161/161 (100%)	161/161 (100%)	161/161 (100%)

Regression analysis results for Veri-Q MGD-2001 fingerstick results vs. Reference:
 Meter lot #1: $y = 0.99854x - 0.3255$; $R^2 = 0.9962$
 Meter lot #2: $y = 0.9983x + 0.5954$; $R^2 = 0.9954$

Alternative Site Testing Accuracy Study:

To assess the accuracy of alternative site testing, results from the Veri-Q MGD-2001 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-2001 meter against the YSI reference. The results are summarized in the tables below:

For glucose concentrations <75 mg/dL

	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Palm vs. YSI	11/13 (84.6%)	13/13 (100%)	13/13 (100%)
Forearm vs. YSI	12/13 (92.3%)	13/13 (100%)	13/13 (100%)

For glucose concentrations ≥ 75 mg/dL

	within $\pm 5\%$	within $\pm 10\%$	within $\pm 15\%$	within $\pm 20\%$
Palm vs. YSI	81/87 (93.1%)	86/87 (98.9%)	87/87 (100%)	87/87 (100%)
Forearm vs. YSI	81/87 (93.1%)	87/87 (100%)	87/87 (100%)	87/87 (100%)

Regression Analysis Veri-Q MGD-2001 AST vs. YSI:

Professional palm: $y = 1.0013x - 0.0755$; $R^2 = 0.998$

Professional forearm: $y = 0.9934x + 0.5229$; $R^2 = 0.998$

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-2001 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-2001 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-2001 system relative to reference are summarized in the tables below:

Lay-user meter result vs. YSI

For glucose concentrations <75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
3/4 (75%)	4/4 (100%)	4/4 (100%)

For glucose concentrations ≥ 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
118/148 (79.7%)	144/148 (97.2%)	148/148 (100%)	148/148 (100%)

Regression Analysis fingerstick vs. YSI:

Lay user vs. YSI: $y = 0.9863x + 7.7287$; $R^2 = 0.994$

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 their own 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:

Lay-User Veri-Q MGD-2001 vs. YSI

For glucose concentrations <75 mg/dL

	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
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 concentrations ≥ 75 mg/dL

	within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
Palm vs. YSI	83/87 (95.4%)	87/87 (100%)	87/87 (100%)	87/87 (100%)
Forearm vs. YSI	81/87 (93.1%)	87/87 (100%)	87/87 (100%)	87/87 (100%)

Regression Analysis Veri-Q MGD-2001 AST vs. YSI:
 Lay user palm vs. YSI : $y = 0.9982x - 0.0903$; $R^2 = 0.998$
 Lay user forearm vs. YSI: $y = 1.0042x - 0.0114$; $R^2 = 0.998$

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.

N. Instrument Name:

Veri-Q self-testing MGD-2001 Blood Glucose Meter
 Veri-Q plus MGD-2001 Blood Glucose Meter

O. 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 Instrument Performance Characteristics Data Not Covered In the “Performance Characteristics” Section above:

1) Hematocrit study:

The effect of different hematocrit levels was evaluated using venous whole blood samples with hematocrit levels of 20 – 60% (20, 30, 40, 50, and 60%) spiked with glucose to achieve target concentrations of 35, 92.3, 131, 245, and 375 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 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 (65, 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 (40, 78, 142, 285, 467 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) 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.

6) Certificates of Electromagnetic Compatibility (EMC) testing compliance were provided for the MGD-2001 Blood Glucose Monitoring System.

7) 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.

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.