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

A. 510(k) Number:

k141656

B. Purpose for Submission:

New devices

C. Measurand:

Glucose in capillary whole blood from fingertip, forearm, upper arm, palm, thigh and calf.

D. Type of Test:

Quantitative amperometric assay (glucose oxidase).

E. Applicant:

Philosys, Inc.

F. Proprietary and Established Names:

Gmate® Mini Blood Glucose Monitoring System
Gmate® Step 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 - Blood glucose test system, Over-the-Counter

   CGA Glucose oxidase, Glucose

4. Panel:

   Clinical Chemistry - 75

H. Intended Use:

1. Intended use(s):

   Refer to indications for use below.

2. Indication(s) for use:

Gmate® mini Blood Glucose Monitoring System

The Gmate® mini 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, palm, thigh or calf. The Gmate® mini Blood Glucose Monitoring System is intended to be used by a single person and should not be shared with any other person.

The Gmate® mini Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use only) by people with diabetes at home as an aid to monitor the effectiveness of their diabetes management. The Gmate® mini Blood Glucose Monitoring System is NOT intended for the diagnosis or screening of diabetes or for neonatal use. Alternate site testing should be done only during steady state times (when glucose is not changing rapidly).

The Gmate® Blood Glucose Test Strips are for use with the Gmate® mini Blood Glucose Monitoring System only for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, thigh or calf.

Gmate® STEP Blood Glucose Monitoring System

The Gmate® STEP 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, palm, thigh or calf. The Gmate® STEP Blood Glucose Monitoring System is intended to be used by a single person and should not be shared with any other person.

The Gmate® STEP Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use only) by people with diabetes at home as an aid to monitor the effectiveness of their diabetes management. The Gmate® STEP Blood Glucose Monitoring System is NOT intended for the diagnosis or screening of diabetes or for neonatal use. Alternate site testing should be done only during steady state times (when glucose is not changing rapidly).

The Gmate STEP includes a pedometer feature that allows the user to count the number of steps they take.

The Gmate® Blood Glucose Test Strips are for use with the Gmate® STEP Blood Glucose Monitoring System only for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, thigh or calf.

3. Special conditions for use statement(s):

For *in vitro* diagnostic use only.

For over the counter use.

Not for neonatal use.

Do NOT use on patients who are critically ill, in shock, dehydrated or hyperosmolar.

Not for use in critically ill patients.

Not for screening or diagnosis of diabetes mellitus.

Alternative site testing (AST) should not be used to calibrate continuous glucose monitors (CGMs) nor for use in insulin dose calculations.

AST testing should only be done during steady-state times (when glucose is not changing rapidly).

Single-patient use systems are for use on single patients only and should not be shared.

Use only fresh capillary whole blood.

4. Special instrument requirements:

   Gmate mini Blood Glucose Meter

   Gmate STEP Blood Glucose Meter

I. Device Description:

The Gmate mini and Gmate STEP Blood Glucose Monitoring Systems consist of a Gmate mini or STEP glucose meter and Gmate test strips. Each BGMS kit contains the mini or STEP meter, lithium battery, carrying case, neck strap, user's guide, quick guide and log book. Gmate test strips and Gmate control solutions are not provided with the kit. Three levels of control solutions (levels 1, 2 and 3) and test strips are available for purchase.

The Gmate™ mini and Gmate™ STEP Blood Glucose Monitoring Systems are identical in all features, except in color, weight, and the Gmate™ Step BGMS has a pedometer feature that uses a piezoelectric sensor to count steps.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   CareSens N Blood Glucose Monitoring System

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

   k083468

3. Comparison with predicate:

Similarities		
Item	Gmate® mini and Step Blood Glucose Monitoring System Candidate Device (k141656)	CareSens N Blood Glucose Monitoring System; Predicate Device (k083468)
Intended Use	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

Similarities		
Item	Gmate® mini and Step Blood Glucose Monitoring System Candidate Device (k141656)	CareSens N Blood Glucose Monitoring System; Predicate Device (k083468)
Assay Method	Electrochemical	Same
Detection Method	Amperometry	Same
Enzyme	Glucose oxidase	Same
Mediator	Potassium ferricyanide	Same
Test Time	5 seconds	Same
Calibration (code method)	Auto-coding	Same
Glucose Measurement Unit	mg/dL (pre-set at the factory) or mmol/L	Same
Measuring Range (mg/dL)	20 to 600	Same
Sample Volume (µL)	0.5	Same
Hematocrit Range (%)	20 to 60	Same
Battery Life	1000 tests	Same
Operating Temperature	50 to 104 ºF (10 to 40 ºC)	Same
Operating Humidity	10 to 90% R.H.	Same
Data Transfer	Diabetes management software via interface cable.	Same
Meter Life	Five years	Same
Results Display	LCD	Same

Differences		
Item	Device	Predicate
AST sites	Fresh capillary whole blood from fingertip, forearm, upper arm, palm, thigh or calf.	Fresh capillary whole blood from fingertip, forearm, palm, thigh or calf.
Memory Capacity	500 test results with date and time.	250 test results
Power Source	One 3.0 V lithium battery (disposable, type CR2032)	Two 3.0 V lithium batteries (disposable, type CR2032)
Setting Mode	Year, Month, Day, Hour, Minute, and Unit (mg/dL or mmol/L).	Year, Month, Day, Time format, Hour, Minute, Unit (mg/dL or mmol/L), Sound on/off, Alarm, and Post-Meal Flagging.
Size	61.7 X 36.7 X 15.8 (mm)	93 X 47 X 15 (mm)
Weight	Gmate® step: 30g Gmate® mini: 24g	51.5g (with batteries)

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

CLSI EP05-A2: Evaluation of precision performance of quantitative measurement methods; 2004.

CLSI EP06-A: Evaluation of the Linearity Quantitative Analytical Method; 2005.

CLSI EP07-A2: Interference Testing in Clinical Chemistry; 2005.

CLSI EP09-A2-IR: Method Comparison and bias estimation using patient samples; 2002.

CEN13640: Stability testing of in vitro diagnostic method device.

EN 60601-1-2: 2007: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

EN 55011: 2007 Class B Group 1: Mains Terminal Continuous Disturbance Voltage; Radiated electromagnetic field.

L. Test Principle:

The Gmate® mini and Gmate® STEP Blood Glucose Monitoring Systems are based on measurement of a small electrical current produced by the reaction of glucose in the blood sample with the reagents on the test strip. The current changes with the amount of glucose in the blood sample. The glucose concentration in the sample is calculated based on the electrical current and is displayed on the meter.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   The repeatability study was performed using venous whole blood (hematocrit ranged from 35 to 50%) at five different glucose concentrations. The final glucose concentrations for the blood samples were confirmed by YSI. Each sample was tested fifty times using twenty meters and one lot of test strips by two operators (N=50 per concentration level per operator). A vial of test strips was assigned to each meter. The repeatability study was repeated with two more test strip lots. The results are summarized below:

Gmate mini BGMS

Within-run Precision Summary

Test Strip Lot 1				
Blood Samples	YSI (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	49	48.4	4.6	9.4
Level 2	101	103.7	3.9	3.7
Level 3	133	133.2	3.6	2.7
Level 4	237	236.5	3.9	1.7
Level 5	378	376.0	4.0	1.1

Test Strip Lot 2				
Blood Samples	YSI (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	49	47.7	4.4	9.2
Level 2	101	104.1	4.0	3.8
Level 3	133	134.8	3.8	2.8
Level 4	237	236.3	3.7	1.6
Level 5	378	376.2	3.9	1.0

Test Strip Lot 3				
Blood Samples	YSI (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	49	47.5	4.4	9.3
Level 2	101	103.2	4.2	4.0
Level 3	133	134.2	3.9	2.9
Level 4	237	236.3	3.6	1.6
Level 5	378	376.2	3.9	1.0

Intermediate precision studies were performed using three levels of control solutions. Each sample was tested on twenty meters using three lots of test strips for twenty days. A vial of test strips was assigned to each meter. Each day each sample was tested using a meter/test strip system in two runs and in triplicate per run (N=60 per run per concentration level). The between-day precision study was repeated with two

more test strip lots. The results are summarized below:

Between-day Precision Summary

Test Strip Lot 1			
Control Solution	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	45.2	0.6	1.4
Level 2	105.2	0.6	0.5
Level 3	316.0	1.9	0.6

Test Strip Lot 2			
Control Solution	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	45.0	0.7	1.6
Level 2	105.5	0.6	0.5
Level 3	316.3	1.6	0.5

Test Strip Lot 3			
Control Solution	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	45.9	1.0	2.3
Level 2	105.2	0.8	0.8
Level 3	315.1	1.8	0.6

Gmate Step BGMS

Within-run Precision Summary

Test Strip Lot 1				
Blood Samples	YSI (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	44	43.6	3.2	7.3
Level 2	101	102.5	2.6	2.6
Level 3	128	132.1	3.8	2.9
Level 4	225	231.3	5.6	2.4
Level 5	355	361.9	6.1	1.7

Test Strip Lot 2				
Blood Samples	YSI (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	44	44.3	3.3	7.5
Level 2	101	105.2	3.4	3.3
Level 3	128	134.6	3.3	2.4
Level 4	225	235.3	3.1	1.3
Level 5	355	375.4	3.1	0.8

Test Strip Lot 3				
Blood Samples	YSI (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	44	45.4	3.2	7.0
Level 2	101	105.1	3.2	3.1
Level 3	128	135.4	3.1	2.3
Level 4	225	234.5	3.1	1.4
Level 5	355	375.2	3.5	0.9

Intermediate precision studies were performed using three levels of control solutions. Each sample was tested on twenty meters using three lots of test strips for twenty days. A vial of test strip was assigned to each meter. Each day each sample was tested using a meter/test strip system in two runs and in triplicate per run (N=60 per run per concentration level). The between-day precision study was repeated with two more test strip lots. The results are summarized below:

Between-day Precision Summary

Test Strip Lot 1			
Control Solution	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	44.9	0.5	1.1
Level 2	104.9	0.8	0.8
Level 3	314.8	3.2	1.0

Test Strip Lot 2			
Control Solution	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	45.5	1.0	2.1
Level 2	105.4	0.9	0.8
Level 3	314.3	2.2	0.7

Test Strip Lot 3			
Control Solution	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	45.1	0.7	1.6
Level 2	104.7	0.7	0.7
Level 3	315.6	1.7	0.5

b. Linearity/assay reportable range:

Fourteen venous whole blood samples were prepared by mixing a low glucose concentration blood sample (7.6 mg/dL) and a high glucose concentration blood sample (634 mg/dL) to cover the device measuring range. Glucose concentrations used with 3 test strip lots (7.6, 17.4, 27.2, 46.8, 66.4, 76.2, 86.0, 164.4, 242.7, 321.1, 399.5, 477.9, 556.2 and 634.6 mg/dL) were confirmed by YSI. The study was performed using ten meters and one vial of test strips from one lot in five replicates. The linearity study was repeated with two more test strip lots. The results of linear regression analysis are summarized below:

Gmate mini BGMS

Test Lot Number	Slope	Intercept	Correlation Coefficient (R^2)
One	1.0007	0.7626	0.9999
Two	1.0005	0.2366	0.9999
Three	1.0021	0.0869	0.9999

Gmate Step BGMS

Test Lot Number	Slope	Intercept	Correlation Coefficient (R^2)
One	0.9982	0.4221	0.9999
Two	0.9956	1.2944	0.9999
Three	0.9965	0.2947	0.9999

Based on the linearity study, the sponsor claims a measuring range of 20 to 600 mg/dL for the two devices.

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

Traceability – The candidate BGMS devices are traceable to NIST SRM 917b.

Value assignment – The Gmate Control Solutions, available in three levels 1, 2 and 3, were cleared under k113636. Value assignment was reviewed and established under k113636.

Control Stability - The Gmate Control Solutions, available in three levels 1, 2 and 3, were cleared under k113636. The sponsor provided Gmate Control Solutions stability studies. The study protocols and acceptance criteria for opened and closed vial stability were reviewed and found acceptable. Gmate Control Solutions have a shelf life of 12 months and are stable for 90 days after opening when stored at 39.2°F to 86°F (4°C to 30°C).

Test Strip Stability - The Gmate Test Strips Stability Study protocols and acceptance criteria for opened and closed vial stability were reviewed and found acceptable. The unopened test strip vials have a 24 month shelf-life and are stable for 3 months after opening when stored at temperatures between 35.6°F to 89.6°F (2°C to 32°C) and 10 to 90% R.H.

d. Detection limit:

The reportable range is 20 to 600 mg/dL based on the linearity/assay reportable range study above (section M.1.b.).

e. Analytical specificity:

Interference study was designed according to CLSI EP7-A2 guideline on both the Gmate mini BGMS and Gmate

Twenty nine potential endogenous and exogenous interfering substances were evaluated by spiking venous blood with two levels of glucose concentrations, 100 mg/dL and 300 mg/dL (measured by YSI). The blood samples were spiked with the potentially interfering compounds and tested in replicates of five using ten meters (from each of the two candidate devices) and three test strip lots. Five concentrations (including the therapeutic, intermediate and high toxic levels) of the interfering substances were tested. Bias was calculated as the individual percent difference in glucose reading between the test (individual measurements) and control (mean value) concentration groups.

The sponsor claims no significant interference for the substances and concentrations shown in the table below for both the devices:

Interferent	Highest Concentration tested with <10% interference (mg/dL)
Acetaminophen	20
Bilirubin	40
Ascorbate	3
Uric Acid	20
Maltose	200
Xylose	60
Galactose	1000
Urea	500
Levo-Dopa	4
Methyl-Dopa	2.5
Dopamine	13
Ibuprofen	40
Salicylic acid	50
Tolbutamide	100
Cholesterol	500
Caffeine	50
Fructose	50
Lactose	50
Lipoic Acid	50
Sucrose	50
Hemoglobin	20
Triglycerides	3000
Creatine	30
Gentisic acid	50
Tolazamide	200
Glutathione	12.3
Sodium	3150

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

See lay user study below.

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):

Lay User Results with Capillary Blood from the Fingertip

Two separate user studies were conducted by two sets of 100 lay users and a healthcare professional using fresh capillary blood samples, over seven days using the Gmate mini BGMS and the Gmate STEP BGMS. Labeling was provided only in English and users followed it to perform the testing. The lay user first performed the testing of the finger followed by the healthcare professional performing the testing. Then, immediately after the above tests were completed, venous whole blood samples were collected, plasma separated, and tested on YSI. The samples were tested using one meter and test strip from one lot of test strips (out of three lots). All results were compared to the YSI. Results are summarized below:

Gmate mini BGMS: Glucose Concentration Range: 55.4 to 414 mg/dL

Regression Analysis Lay User testing on BGMS vs YSI

	Slope	Intercept	R^2
Finger (N=100)	0.9999	5.271	0.9974

Lay User testing vs YSI < 75 mg/dL

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Finger (N=16)	6/16 (38%)	13/16 (81%)	16/16 (100%)

Lay User testing vs YSI ≥ 75 mg/dL

	Within ± 5%	Within ± 10%	Within ± %15	Within ± 20%
Finger (N=84)	62/84 (74%)	82/84 (98%)	84/84 (100%)	84/84 (100%)

Gmate STEP BGMS: Glucose Concentration Range: 58.9 to 452 mg/dL

Regression Analysis Lay User testing on BGMS vs YSI

	Slope	Intercept	R^2
Finger (N=100)	0.9889	0.1675	0.996

Lay User testing vs YSI < 75 mg/dL

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Finger (N=16)	14/16 (8%)	15/16 (94%)	16/16 (100%)

Lay User testing vs YSI ≥ 75 mg/dL

	Within ± 5%	Within ± 10%	Within ± %15	Within ± 20%
Finger (N=84)	72/84 (86%)	80/84 (95%)	84/84 (100%)	84/84 (100)

Alternative Site Testing by Lay User

Two separate AST testing studies by Lay Users using the Gmate mini BGMS and the Gmate STEP BGMS were performed by two distinct sets of 100 participants and results were compared to the YSI. The testing on YSI was performed by a healthcare professional using venous blood collected within 5 minutes of testing by lay users. The samples were tested using one meter and test strip from one lot of test strips (out of three lots). Results are summarized below:

Gmate mini BGMS: Glucose Concentration Range: 55.5 to 438 mg/dL

Regression Analysis Lay User testing on BGMS vs YSI

	Slope	Intercept	R^2
Forearm	1.0207	5.6328	0.9969
Upper arm	1.019	5.1866	0.9962
Thigh	1.0089	6.7504	0.9963
Calf	1.0305	2.8831	0.9977
Palm	1.0233	4.7435	0.9972

Lay User testing on BGMS vs YSI < 75 mg/dL

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Forearm	5/8 (63%)	8/8 (100%)	8/8 (100%)
Upper arm	7/8 (88%)	8/8 (100%)	8/8 (100%)
Thigh	7/8 (88%)	8/8 (100%)	8/8 (100%)
Calf	6/8 (75%)	8/8 (100%)	8/8 (100%)
Palm	7/8 (88%)	8/8 (100%)	8/8 (100%)

Lay User testing on BGMS vs YSI ≥ 75 mg/dL

	Within ± 5%	Within ± 10%	Within ± %15	Within ± 20%
Forearm	39/92 (42%)	79/92 (86%)	92/92 (100%)	92/92 (100%)
Upper arm	42/92 (46%)	84/92 (91%)	92/92 (100%)	92/92 (100%)
Thigh	41/92 (45%)	79/92 (86%)	91/92 (99%)	92/92 (100%)
Calf	56/92 (61%)	83/92 (90%)	90/92 (98%)	92/92 (100%)
Palm	45/92 (49%)	79/92 (86%)	90/92 (98%)	92/92 (100%)

Gmate STEP BGMS: Glucose Concentration Range: 58.6 to 450 mg/dL

Regression Analysis Lay User testing on BGMS vs YSI

	Slope	Intercept	R^2
Forearm	1.0257	5.5368	0.996
Upper arm	1.014	2.7344	0.998
Thigh	1.009	4.6647	0.9963
Calf	1.0094	6.0665	0.9963
Palm	1.0275	3.0415	0.9961

Lay User testing on BGMS vs YSI < 75 mg/dL

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Forearm	5/8 (63%)	8/8 (100%)	8/8 (100%)
Upper arm	5/8 (63%)	8/8 (100%)	8/8 (100%)
Thigh	6/8 (75%)	8/8 (100%)	8/8 (100%)
Calf	7/8 (88%)	8/8 (100%)	8/8 (100%)
Palm	7/8 (88%)	8/8 (100%)	8/8 (100%)

Lay User testing on BGMS vs YSI ≥ 75 mg/dL

	Within ± 5%	Within ± 10%	Within ± %15	Within ± 20%
Forearm	48/92 (52%)	82/92 (89%)	88/92 (96%)	92/92 (100%)
Upper arm	68/92 (74%)	92/92 (100%)	92/92 (100%)	92/92 (100%)
Thigh	51/92 (55%)	81/92 (88%)	88/92 (96%)	92/92 (100%)
Calf	53/92 (58%)	84/92 (91%)	88/92 (96%)	92/92 (100%)
Palm	46/92 (50%)	80/92 (87%)	90/92 (98%)	92/92 (100%)

Usability studies were conducted to assess the readability of the labeling of the two candidate devices. These two usability studies were performed 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.

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   Expected blood glucose values for people without diabetes is cited from the literature and presented in the labeling as follows:

Before Eating: <100 mg/dL

2 hours after meals: <140 mg/dL

*American Diabetes Association (2014). Standards of Medical Care in Diabetes - 2014. Diabetes Care, 37 (Supplement 1): January 2014: S14–S80.

N. Instrument Name:

Gmate™ mini Blood Glucose Meter

Gmate™ STEP Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

   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___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 _____

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 tests with the two candidate devices are intended to be used with capillary whole blood from finger, palm, upper arm, forearm, palm, thigh and calf. The capillary whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   The Gmate mini and Gmate Step meters are autocoding devices. The devices are factory calibrated and require no additional calibration by the user. The labeling includes instructions for the user to confirm that the code number on the meter screen matches the code number on the test strip vial label.

6. Quality Control:

   The sponsor recommends the use of Level 1, Level 2 and Level 3 Gmate control solutions with these two Gmate™ BGM systems. Control solutions are not included in the kit. These controls can be purchased using the contact information provided in the user manual. When the test strip is inserted into the glucose meter, control material can

be measured by following the instructions for "Control Solution Testing" provided in the user guide for the meter. The Gmate™ mini and Gmate™ Step meters do not recognize and mark the control result.

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

1) Disinfection efficacy studies were performed on the material components of the two meters with the disinfectant, CaviWipes (EPA registration #46781-8). The study results indicated complete inactivation of the hepatitis B virus (HBV). Additionally, robustness studies were conducted and the study results showed no change in the performance or in the external materials of the two candidate meters after 260 cleaning and disinfection cycles (each cycle includes one cleaning and one disinfection step) designed to simulate 4 years of single-patient device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

2) A readability assessment of the Gmate mini, Gmate STEP User Guide and test strip insert showed a Flesch-Kincaid reading level of 4.7^{th} , 4.4^{th} and 6.9^{th} grade level, respectively . The readability assessment of the Gmate Diabetes Management Software User's Guide showed a Flesch- Kincaid reading grade level of 7.7.

3) Temperature and humidity studies: To evaluate performance of these two systems under the extremes of the recommended temperature and humidity conditions, testing was performed using 3 concentrations of patient samples (~ 45 mg/dL, 110 mg/dL and 310 mg/dL) at temperatures of 50^{o}F (10^{o}C), 75.2 ^{o}F (24^{o}C), and 89.6 ^{o}F (32^{o}C), and RH of 10%, 50% and 90%; each temperature was tested at all three RH conditions. The results demonstrated that that the Gmate™ mini and Gmate™ Step BGMS produces accurate results over the claimed range of operating temperature and humidity conditions.

4) A altitude study was conducted using spiked venous blood samples at four glucose concentrations (70, 120, 220, and 370 mg/dL), and tested in a hyperbaric chamber set to simulate atmospheric conditions at sea level (zero feet) and 10,000 feet. Each sample was tested three times using one test strip lot. Each venous blood sample was also tested by the YSI 2300 analyzer. The meter readings obtained were compared to the YSI method. Based on the data, the sponsor claims that the Gmate™ mini and Gmate™ Step BGMS can be used at altitudes up to 10,000 feet.

5) A hematocrit study was conducted to evaluate potential interference from hematocrit using five different hematocrit (Hct) levels (20, 30, 40, 50, and 60%) across the glucose measuring range. At each hematocrit level, five blood samples at glucose concentration of 50, 100, 150, 230, and 330 mg/dL were tested against the YSI method. Each sample was tested (in replicates of ten) on ten meters using one lot of test strips and the values were compared to the YSI value of the 40% Hct sample. The results demonstrated that the Gmate™ mini and Gmate™ STEP BGMS produces accurate results over the claimed hematocrit range of 20 to 60% Hct.

6) A minimum sample volume study was performed to verify the test strip minimum sample volume of 0.5 µL for the Gmate™ mini and Gmate™ STEP BGMS. Venous blood from donors was collected and the glucose levels were adjusted to 40, 70, 125, 250, and 450 mg/dL. Blood at each concentration was applied to strips (in replicates of

five) at four target sample volumes of 0.3 µL, 0.5 µL, 0.7 µL and 1.0 µL. Protocols and acceptance criteria were provided and found to be acceptable. The study results showed that the minimum sample volume of 0.5 µL produced accurate results.

7) Pedometer function: The only difference between the Gmate mini and the Gmate STEP is the built-in pedometer function in the G mate STEP. The pedometer feature allows the user to count the number of steps they take. The Gmate STEP utilizes a Piezo electric sensor to count the number of steps taken. Software validation documentation was reviewed and found to be acceptable to support this feature.
8) EMC testing was evaluated and certified by IST Co., Ltd., and a declaration of conformity was issued for each of the two candidate meters.
9) The Customer Care Service Center is available 24/7, 365 days a year. The toll free phone number is 1-855-464-6283.

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.