

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

A. 510(k) Number:

k150299

B. Purpose for Submission:

Modification to the device to add compatibility with Android mobile smartphones, specifically Samsung Galaxy S3, S4, S5.

C. Measurand:

Glucose in fresh capillary whole blood from the fingertip, forearm, upper arm, palm, thigh or calf.

D. Type of Test:

Quantitative, Amperometric method, Glucose Oxidase.

E. Applicant:

Philosys, Inc.

F. Proprietary and Established Names:

Gmate SMART Blood Glucose Monitoring System

G. Regulatory Information:

Regulation Section	Classification	Product Code	Panel
21 CFR 862.1345	Class II	CGA, Glucose Oxidase,	Clinical Chemistry (75)
21 CFR 862.1345	Class II	NBW, System, Test, Blood Glucose, Over the Counter	Clinical Chemistry (75)
21 CFR 862.2100	Class I limitations of exemption 862.9(c)(5)	JQP, Calculator/Data Processing Module, For Clinical Use	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indication(s) for use below.

2. Indication(s) for use:

The Gmate® SMART Blood Glucose Monitoring System is intended 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® SMART Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The Gmate® SMART Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home to monitor the effectiveness of diabetes control. The Gmate® SMART should not be used for the diagnosis of 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® SMART Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, thigh or calf.

The Gmate™ SMART App is a component of the Gmate® SMART Blood Glucose Monitoring System and is intended to be used by people with diabetes at home as an aid to monitor and track the effectiveness of their diabetes management. The Gmate™ SMART App allows the user to view their glucose test results and store a lifetime of results. The user may e-mail their glucose test results to their healthcare provider to help them review, analyze, and evaluate their glucose test results to support an effective diabetes management program. The user can also graph and trend their glucose test results to provide an outlook of their diabetes management.

3. Special conditions for use statement(s):

- For single-patient use only
- 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
- Use only fresh capillary whole blood, not for use with serum or plasma
- Alternative site testing (AST) 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:

Gmate® SMART Blood Glucose Meter

Apple iPhone, iPod Touch, and iPad with iOS operating system (iOS version 5.0 or higher)

Samsung Galaxy S3, S4, S5 phone with Android operating system (Android version 4.0 or higher)

I. Device Description:

The Gmate® SMART Blood Glucose Monitoring System consists of a glucose meter, test strips, and control materials (3 levels – Level 1, Level 2, Level 3). The Gmate SMART meter does not require coding or calibration, batteries, or settings based on user input, and is powered on by plugging it into the headphone jack of an Apple/Android device including an Apple iPhone, iPod Touch, or iPad with iOS operating version 5.0 or higher, or a Samsung Galaxy S3, S4, S5 phone with Android operating system version 4.0 (ice cream sandwich) or higher. The user inserts the test strip into the meter, applies blood or control solution to the strip and the App begins a 5 seconds count down prior to displaying a test result on the Apple or Android device. The GmateSMART App converts the signal generated from the meter and test strip and displays the test result on the Apple/Android device. The Gmate SMART App is an integral component of the Gmate SMART Blood Glucose Monitoring System and allows the user to view their glucose test results and store a lifetime of results. Using the App, a user can graph and trend their glucose test results to provide an outlook of their diabetes management.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Gmate® SMART Blood Glucose Monitoring System

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

k131230

3. Comparison with predicate:

Similarities		
Item	Predicate Device: Gmate SMART Blood Glucose Monitoring System (k131230)	Candidate Device: Gmate SMART Blood Glucose Monitoring System (k150299)
Intended Use	Intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood	same

Similarities		
Item	Predicate Device: Gmate SMART Blood Glucose Monitoring System (k131230)	Candidate Device: Gmate SMART Blood Glucose Monitoring System (k150299)
	samples drawn from the fingertips, forearm, upper arm, palm, thigh or calf as an aid to monitor the effectiveness of diabetes control in people with diabetes.	
Detection Method	Amperometry: current is generated by oxidation of reduced mediator.	same
Enzyme	Glucose Oxidase	same
Test range	20-600 mg/dL	same
Hematocrit Range	20-60%	same
Test Time	5 seconds	same
Sample Volume	0.5 µl	same
Operating Conditions Temperature & Humidity Range	50-104 ⁰ F (10-40 ⁰ C), 10-90% humidity	same
Coding	No Coding	same
Memory capability	7, 14, 30-day average and a lifetime of memory	same
Power	from smart phone/ mobile device	same
Battery life	N/A	same
Size: LxWxH (mm)	42.7 x 21 x 8.8	same
Weight	4.2g	same
Software	Gmate® SMART Application	same

Differences		
Item	Predicate Device (k131230)	Candidate Device (k150299)
Software Characteristics	Device compatible with the iPhone iOS operating system	Device compatible with iPhone iOS and Android operating systems versions 4.0 (ice cream sandwich) or higher on the Samsung Galaxy S3, S4, S5 phones

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

CLSI-FDA EP05-A2:2005 Evaluation of precision performance of quantitative measurement methods; Approved guideline

CLSI-FDA EP06-A:2009 Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach

CLSI EP09-A3:2013 Measurement procedure comparison and bias estimation using patient samples; Approved guideline

CEN 13640 Stability testing of in vitro diagnostic medical device

EN 61010-1:2001 (2nd Edition) Safety Requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements

EN 61010-2-101:2002 Safety Requirements for electrical equipment for measurement, control and laboratory use Part 2-101: Particular requirements for In Vitro Diagnostic (IVD) Medical Equipment.

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

CLSI-FDA EP07-A2:2007 Interference Testing in Clinical Chemistry; Approved Guideline

L. Test Principle:

This device is an in vitro diagnostic product intended for the measurement of the glucose concentration of human capillary whole blood. The principle of the test is based on the measurement of a small electrical current produced by the reaction of glucose in the blood sample with the reagents (including a glucose oxidase enzyme) on the test strip. This reaction produces an electrical current which is proportional to the amount of glucose present in the blood sample. The current is detected by the meter and converted by the App to a blood glucose value which is displayed to the user.

M. Performance Characteristics (if/when applicable):

All performance testing for this device was conducted using mobile platforms and operating system appropriately representative of the mobile platforms and operating systems for use with this device (Samsung Galaxy S3, S4 and S5 phones and Android operating system version 4.0 or higher).

1. Analytical performance:

a. *Precision/Reproducibility:*

Within run precision was evaluated using venous whole blood spiked with an aqueous glucose solution or allowed to glycolyze to generate samples within five different glucose concentration ranges (30-50, 51-110, 111-150, 151-200 and 251-400 mg/dL). Three test strip lots and 20 meters were used for this study. For each test strip lot, each sample was tested 50 times by each of two operators. The mean values and coefficients of variation were calculated for each sample and are summarized below.

Glucose level (mg/dL)	Test Strip Lot	YSI Plasma (mg/dL)	n	Mean Meter Reading (mg/dL)	SD (mg/dL)	%CV
30-50	1	42	100	44.8	2.3	5.2
	2		100	45.1	2.4	5.2
	3		100	45.0	2.1	4.6
51-110	1	103	100	105.1	2.3	2.2
	2		100	104.8	2.4	2.3
	3		100	104.7	2.3	2.2
111-150	1	123	100	125.6	1.9	1.5
	2		100	124.9	2.1	1.7
	3		100	125.3	2.4	1.9
151-250	1	229	100	230	4.6	2.0
	2		100	229	4.0	1.7
	3		100	229.7	4.9	2.1
251-400	1	331	100	340.1	3.9	1.2
	2		100	338.7	4.4	1.3
	3		100	339.9	4.1	1.2

Intermediate precision was evaluated over 20 days using three levels of control solution and 20 Gmate SMART Meters. Each sample was measured six times per day using each of three test strip lots. The mean values and coefficients of variation were calculated for each sample and are summarized below.

Glucose Level (mg/dL)	Strip Lot	n	Mean Meter Reading (mg/dL)	SD (mg/dL)	%CV
35-65	1	12	45.4	0.7	1.5
	2	12	45.1	0.9	0.9
	3	12	44.7	0.8	1.7
75-125	1	12	104.8	0.7	1.5
	2	12	104.7	0.9	0.9
	3	12	104.3	0.8	0.8

225-375	1	12	314.1	2.1	0.7
	2	12	314.7	1.8	0.6
	3	12	315.1	1.8	0.6

b. *Linearity/assay reportable range:*

Linearity was evaluated by preparing high and low glucose venous blood samples and performing a dilution to achieve 14 evenly spaced glucose levels from 7.6 to 634.6 mg/dL (7.6, 17.4, 27.2, 46.8, 66.4, 76.2, 86, 164.4, 242.7, 321.1, 399.5, 477.9, 556.2, 634.6 mg/dL) as measured by the comparator method (an established laboratory reference method, YSI 2300 analyzer). Each level was tested in replicates of 5 with each of three test strip lots, resulting in a total of 15 replicates for each glucose level. The values from the Gmate SMART Blood Glucose Meter were compared to those obtained from an established laboratory reference method (YSI 2300 analyzer). The results from regression analysis are summarized below:

Lot 1: $y = 0.997x + 0.4738$, $R^2 = 0.9999$

Lot 1: $y = 0.9971x - 0.3625$, $R^2 = 0.9999$

Lot 1: $y = 0.9971x - 0.3239$, $R^2 = 0.9999$

The results of the study support the sponsor's claimed glucose measurement range of 20 to 600 mg/dL. The meter displays "Low" with glucose values below 20mg/dL, and "Hi" with glucose values over 600 mg/dL.

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

Traceability

The system is traceable to NIST standard reference material 917b.

Stability

Test strip closed vial stability:

Stability protocols and acceptance criteria were reviewed and found to be acceptable to support a shelf life of 24 months when stored at a temperature ranging from 36°F-86°F (2°C to 30°C) and between 10%-90% relative humidity.

Test strip open vial stability:

Stability protocols and acceptance criteria were reviewed and found to be acceptable to support an open-vial use life of 3 months at a temperature ranging from 36°F-86°F (2°C to 30°C) and between 10%-90% relative humidity.

Control Solution Stability

The control solutions compatible for use with the current device (Gmate Control Solutions) were previously cleared, and stability and value assignment were established in k113636. Control solutions are stable for 3 months when stored in a

cool, dry out of direct sunlight between 40°F to 86°C (4°C to 30°C). Once opened the controls are stable for 3 months when closed tightly after use and stored between 40°F to 86°C (4°C to 30°C).

d. Detection limit:

The reportable range for the Gmate SMART Blood Glucose Monitoring System is 20 to 600 mg/dL. This range was verified by the linearity study (see Section M.1.b, above).

e. Analytical specificity:

Twenty-three endogenous and exogenous substances were screened for interference by spiking each substance into a venous whole blood sample altered to contain either a low glucose value of 80-120 mg/dL or a high glucose value of 300-350 mg/dL. The high and low glucose blood samples spiked with a potentially interfering substance was diluted with unspiked sample to generate 5 total samples (including the unspiked sample) with different concentrations of the potentially interfering substance. Each sample was tested in replicates of 5 on each of 3 strip lots. The % difference between the spiked samples and the control sample with no substance was calculated. The sponsor defined no significant interference as bias within $\pm 10\%$.

The system exhibits no significant interference from the following substances up to the concentrations listed below:

Potentially interfering substance	Highest tested concentration with no significant interference (mg/dL)
Acetaminophen	20
Ascorbate	3
Bilirubin	40
Caffeine	50
Cholesterol	500
Dopamine	13
EDTA	640
Fructose	50
Galactose	20
Hemoglobin	20
Ibuprofen	40
Lactose	50
Levo-Dopa	4
Lipoic acid	50

Maltose	360
Methyl-Dopa	2.5
Salicylic acid	50
Sucrose	50
Tolbutamide	100
Triglycerides	3000
Urea	500
Uric acid	20
Xylose	20

Based on the test results, the sponsor states in the strip package insert: If you are taking acetaminophen (e.g. Tylenol, etc.) or Vitamin C (ascorbic acid) at higher than therapeutic doses (>20 mg/dL acetaminophen or >3 mg/dL ascorbic acid) you may get inaccurate results using this meter.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

A user evaluation study was performed with 100 lay-users to determine whether glucose readings from the fingertip, upper arm, forearm, thigh, calf and palm obtained by a lay-user provided with only the device labeling as testing instructions were comparable to results from venous whole blood measured using a laboratory glucose reference method. The labeling provided to the users was in English only. Each participant performed their own fingerstick or testing of an alternative site using the device and instructions in the proposed labeling, including the user manual. The samples ranged in glucose concentration from 55.9 to 449 mg/dL (as measured with the laboratory reference method, the YSI 2300 analyzer). Results are summarized below:

Fingertip capillary blood:

System accuracy results for glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
12 / 16 (75%)	14 / 16 (88%)	16 / 16 (100%)

System accuracy results for glucose concentration ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
77 / 84 (92%)	83 / 84 (99%)	84 / 84 (100%)	84 / 84 (100%)

Upper Arm capillary blood:

System accuracy results for glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
6 / 8 (75 %)	8 / 8 (100 %)	8 / 8 (100 %)

System accuracy results for glucose concentration ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
79/ 92 (86%)	92 / 92 (100 %)	92 / 92 (100 %)	92 / 92 (100 %)

Forearm capillary blood:

System accuracy results for glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
6 / 8 (75 %)	8 / 8 (100 %)	8 / 8 (100 %)

System accuracy results for glucose concentration ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
51 / 92 (55 %)	83 / 92 (90 %)	88 / 92 (96 %)	92 / 92 (100 %)

Thigh capillary blood:

System accuracy results for glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
6 / 8 (75 %)	8 / 8 (100 %)	8 / 8 (100 %)

System accuracy results for glucose concentration ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
61 / 92 (66 %)	83 / 92 (90 %)	91 / 92 (99 %)	92 / 92 (100 %)

Calf capillary blood:

System accuracy results for glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
7 / 8 (88 %)	8 / 8 (100 %)	8 / 8 (100 %)

System accuracy results for glucose concentration ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
55 / 92 (60 %)	84 / 92 (91 %)	88 / 92 (96 %)	92 / 92 (100 %)

Palm capillary blood:

System accuracy results for glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
7 / 8 (88 %)	8 / 8 (100 %)	8 / 8 (100 %)

System accuracy results for glucose concentration ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
46 / 92 (50 %)	81 / 92 (88%)	90 / 92 (98 %)	92 / 92 (100 %)

b. Matrix comparison:

Not applicable. Capillary whole blood is the only indicated matrix.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

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

The sponsor provided results of a readability study that indicated that the user manual, test strip labeling, and control solution labeling is at an 8th grade reading level or below.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

The sponsor included the following Expected Values from the literature¹ for normal glucose levels in their test strip labeling:

Before eating < 100 mg/dL

Two hours after meals < 140 mg/ dL

¹ American Diabetes Association (2015). Standards of Medical Care in Diabetes – 2015. Diabetes Care, 38 (Supplement 1): January 2015:S10-S93.

N. Instrument Name:

Gmate SMART Blood Glucose Monitoring System

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 ___X___ or No _____

2. Software:

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

Yes ___X___ or No _____

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:

This device is intended to be used with capillary whole blood from the finger, palm, or forearm only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

No user-entered coding or calibration is required for this device. Coding is accomplished by the storage of code numbers and test strip lot-specific information in the meter, which can be controlled because the meter manufacturer also manufactures the test strips for this device. Each test strip code is embedded in the test strips by laser carving each test strip with a code number pattern, which is recognized by the meter and used for

calibration.

6. Quality Control:

Glucose control solutions at three different concentrations (Levels 1, 2, and 3) are provided with one kit configuration of the device and also available separately. Device kit configurations that do not include control solutions indicate that the control solutions are required but not included and must be purchased separately. 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. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. **Hematocrit Study:** The effect of different hematocrit levels on the performance of the Gmate SMART Blood Glucose Monitoring System was evaluated using whole blood samples manipulated to contain hematocrit levels of 20, 30, 40, 50, and 60% and spiked with glucose or allowed to glycolyze to achieve concentrations between 50 and 325 mg/dL. Each sample was then tested 10 times and the individual values were compared with those obtained from an established laboratory reference analyzer (YSI 2300 analyzer). The device demonstrated adequate performance to support the hematocrit claim of 20% and 60%.
2. **Altitude study:** Venous whole blood samples were collected from four blood donors and spiked with glucose into four concentration levels (70, 130, 230 and 380 mg/dL). Blood glucose target concentrations were then verified by comparison to an accepted laboratory reference method (YSI 2300 analyzer). The study was performed using a hyperbaric chamber to simulate altitudes of 3000, 6000 and 10,000 feet. The results demonstrate acceptable bias relative to the reference method to support the claims that the Gmate SMART blood glucose monitoring system can be used at altitudes up to 10,000 feet.
3. **Temperature and humidity studies:** The sponsor performed temperature and humidity studies using blood samples with three target concentrations of glucose (<75 mg/dL, 100-200 mg/dL and > 300mg/dL) to evaluate temperatures ranging from 50°F to 104°F and relative humidity from 10% to 90%. Meter results were compared to results from an accepted laboratory reference method (YSI 2300 analyzer). Four temperature and humidity combinations, including low temperature/low humidity, low temperature/high humidity, high temperature/low humidity and high temperature/high humidity were tested using three lots of test strips. No significant effect (relative to an established laboratory reference method, YSI 2300 analyzer) was observed with any of the temperature and humidity combinations tested. The results support the claims in the labeling that the system can be used in temperatures of 50°F to 104°F with relative humidity of 10 to 90%.
4. **Sample Volume Studies:** The sponsor performed sample volume studies using venous blood altered to five target glucose concentrations (50, 70, 120, 230 and 430 mg/dL). At each target concentration, samples of different volumes (0.3, 0.5, 0.7 and 1.0 µl) were

measured with the device and compared to results from an accepted laboratory reference method (YSI 2300 analyzer). The results support a minimal sample volume of 0.5µl.

5. **Infection Control Studies:** The Gmate SMART Blood Glucose Monitoring System is intended for single-patient use. The sponsor stated that the disinfection efficacy for the meter was evaluated in k131230 and that the materials comprising the meter are identical to k131230. CaviWipes disinfecting towelettes (EPA registration # 46781-8), were validated by an outside testing laboratory to demonstrate complete inactivation of live virus for use with the Samsung Galaxy S3, S4 or S5 phones. The sponsor also demonstrated that there was no change in performance of the system or in the external materials of the Gmate SMART meter or Samsung Galaxy S3, S4 or S5 phones after 520 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.
6. **Usability Questionnaire:** A usability test was conducted with one hundred lay users. Each user was provided with a Gmate SMART Blood Glucose Monitoring System and the proposed labeling and asked to perform a blood glucose self-test and complete a survey about the ease of use of the device and software. More than 95% of users indicated a level of satisfaction of “Good” or “Very Good” for each question related to usability of the device and the instructions, indicating that there are no areas of concern regarding the usability of the device by the intended users.
7. **Software:** Software documentation was reviewed and demonstrated that the device was developed under appropriate software lifecycle processes.
8. **Electromagnetic Compatibility (EMC) testing:** The sponsor provided documentation certifying that appropriate electromagnetic compatibility testing (EMC) had been performed.
9. Customer service is available 24 hours a day, 7 days a week by calling 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.