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

A. 510(k) Number:

k131230

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose from the fingertips, forearm, upper arm, hand, thigh or calf

D. Type of Test:

Quantitative amperometric assay (Glucose Oxidase)

E. Applicant:

Philosys Co. Ltd.

F. Proprietary and Established Names:

Gmate SMART Blood Glucose Monitoring System
Gmate SMART Application

G. Regulatory Information:

Regulation Section	Classification	Product Code	Panel
21 CFR § 862.1345	Class II	CGA, Glucose Oxidase, glucose	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 to exemption 862.9(c)(5)	JQP, Calculator/data processing module for clinical use	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   Refer to Indications for Use

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, hand, thigh or calf.

   The Gmate® SMART Application 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 Application 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 physician or healthcare professional 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 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
   - For single-patient use only
   - 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:

   Gmate® SMART Meter

   Apple iPhone, iPod Touch, and iPad with iOS operating system

I. Device Description:

The Gmate® SMART Blood Glucose Monitoring System consists of the Gmate SMART meter, Gmate test strips, and Gmate Control Solutions Level 1, 2, and 3. The Gmate control solutions were previously cleared under k113636. The Gmate® SMART meter does not require coding or its own batteries. The Gmate® SMART meter is powered on by plugging it into the headphone jack of the smartphone or mobile device. Users are instructed to insert the test strip into the meter, apply the blood or control solution to the strip, after which the meter will begin the 5 second count down before displaying the test result. The Gmate® SMART Application converts the signal generated from the meter and test strip and displays the test result on the smartphone or mobile device.

The Gmate® SMART Blood Glucose Monitoring System uses the smartphone technology, currently Apple's iOS (with use of the Apple iPhone 3GS, iPhone 4, iPhone 4S, iPhone 5, iPod Touch 4th generation, iPad, and iPad2), to view glucose test results. A simple download of the Gmate® SMART Application, enables use of many functions.

The Gmate® SMART Application 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 Application 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 physician or healthcare professional 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   AgaMatrix, Inc. iBGStar Blood Glucose Monitoring System

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

   k103544

3. Comparison with predicate:

Similarities

Item	Candidate Device Philosys Gmate SMART (k131230)	Predicate device AgaMatrix, Inc. iBGStar (k103544)
Intended Use	Same	Intended for the quantitative measurement of glucose in fresh capillary blood samples.
Detection Method	Same	Amperometry
Enzyme	Same	Glucose Oxidase
Electrode	Same	Carbon
Measuring Range	Same	20 – 600 mg/dL
Acceptable Humidity Range	Same	10 – 90% RH
Hematocrit Range	20 – 60%	20 – 60%
Sample Volume	0.5 µL	0.5 µL
Acceptable Temperature Range	10 – 40° C	10 – 40° C
Coding	Not required	Not required

Differences

Item	Candidate Device Philosys Gmate SMART (k131230)	Predicate device AgaMatrix, Inc. iBGStar (k103544)
Test Time	5 seconds	6 seconds
Software	Gmate SMART Application	iBGStar Diabetes Manager Application
Dimensions: LxWxH (mm)	43x21x9	55x24x10
Weight	4.2 g (without iOS device)	42 g

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

ISO 15197:2003: In Vitro Diagnostic Test Systems-Requirements for Blood Glucose Monitoring Systems for Self-Testing in Managing Diabetes Mellitus

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

CLSI EP06-A: Evaluation of the Linearity Quantitative Analytical Method; Proposed Guideline

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

CLSI EP09-A2-IR: Method Comparison and bias estimation using patient samples; Approved guideline

CEN 13640: Stability testing of in vitro diagnostic method device

EN 55011: 2007 + A1 2007 (Class B): Mains Terminal Continuous Disturbance Voltage; Radiated electromagnetic field

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 61010-1: Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements

EN 61010-2-101: Safety requirements for electrical equipment for measurement, control, and laboratory use, Particular requirements for in vitro diagnostic (IVD) medical equipment.

L. Test Principle:

The Gmate SMART Blood Glucose Monitoring System is an in vitro diagnostic device intended for the measurement of glucose in capillary blood. The principle of the test relies upon a reaction between a specific type of sugar (glucose) in the blood sample and the glucose oxidase in the test strip. This reaction generates a small electrical current. The meter measures the current and calculates the blood glucose level. Combined with the Gmate® SMART App, it displays the test result and stores them on the smartphone or mobile device.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

   The sponsor performed within-run precision studies using EDTA venous whole blood samples spiked to five different glucose concentration ranges (30 to 50, 51 to 110, 111 to 150, 151 to 250, and 251 to 400 mg/dL). The hematocrit of the samples used was 35 to 50%. Fifty samples were prepared at each glucose level, and each sample was analyzed in duplicate for a total of 100 results per glucose level. Two operators collected the results using one test strip lot and twenty meters. Results are summarized below:

Within-run precision for glucose: Lot 1

Glucose Level (mg/dL)	Number of tests	Mean (mg/dL)	SD (mg/dL)	CV (%)
30 – 50	100	40.9	1.3	3.1
51 – 110	100	99.1	2.8	2.9
111 – 150	100	130.7	2.9	2.3
151 – 250	100	229.2	4.4	1.9
251 – 400	100	372.2	9.9	2.7

Within-run precision for glucose: Lot 2

Glucose Level (mg/dL)	Number of tests	Mean (mg/dL)	SD (mg/dL)	CV (%)
30 – 50	100	40.5	1.1	2.8
51 – 110	100	106.3	2.4	2.25
111 – 150	100	131.4	2.6	1.95
151 – 250	100	228.4	3.9	1.7
251 – 400	100	375.3	8.5	2.3

Within-run precision for glucose: Lot 3

Glucose Level (mg/dL)	Number of tests	Mean (mg/dL)	SD (mg/dL)	CV (%)
30 – 50	100	41.5	1.1	2.6
51 – 110	100	106.4	2.2	2.0
111 – 150	100	131.9	2.4	1.8
151 – 250	100	230.5	3.8	1.6
251 – 400	100	375.8	8.1	2.15

Between-day precision was evaluated using three levels of glucose control solutions with concentrations of 35 to 65, 75 to 125, and 225 to 375 mg/dL. Per day, each sample was measured 6 times with three test strip lots and 20 meters. These tests were performed over 20 days, for a total of 120 results per glucose level. Results are summarized below.

Between-day precision for glucose: Lot 1

Glucose Level (mg/dL)	Number of tests	Mean (mg/dL)	SD (mg/dL)	% CV
35 to 65	120	42.1	1.0	2.4
75 to 125	120	104.4	2.5	2.4
225 to 375	120	307.7	6.5	2.1

Between-day precision for glucose: Lot 2

Glucose Level (mg/dL)	Number of tests	Mean (mg/dL)	SD (mg/dL)	% CV
35 to 65	120	40.9	0.9	2.2
75 to 125	120	105.2	1.6	1.6
225 to 375	120	308	3.7	1.2

Between-day precision for glucose: Lot 3

Glucose Level (mg/dL)	Number of tests	Mean (mg/dL)	SD (mg/dL)	% CV
35 to 65	120	42	0.9	2.1
75 to 125	120	105	1.7	1.6
225 to 375	120	308	3.6	1.2

b. Linearity/assay reportable range:

Linearity was evaluated using three test strip lots and 14 mixed pools of venous blood with glucose concentrations at 8, 18, 27, 47, 67, 77, 87, 166, 244, 324, 400, 481, 559, and 635 mg/dL as measured by the YSI reference method. Each level was measured in replicates of five with each of three test strip lots and the values from the Gmate® SMART meter were compared with those obtained from the YSI-2300. Results from regression analysis:

Test strip lot #1: $y = 0.999x + 1.443$; $r^2 = 0.999$

Test strip lot #2: $y = 1.003x + 1.267$; r2 = 0.999

Test strip lot #3: $y = 1.004x + 1.466$; r2 = 0.999

The results of the study support the sponsor's claimed glucose measurement range of 20 - 600 mg/dL.

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

Traceability

The Gmate SMART Blood Glucose Monitoring System is traceable to the YSI 2747 Glucose Standard. The method comparison study was performed using the candidate device and YSI 2300 Glucose Analyzer as the reference method. The controls are prepared at two target concentrations gravimetrically and the glucose concentrations are verified with the YSI reference method.

The primary calibrator is traceable to NIST SRM 917b.

Stability – Gmate Control solutions

The claimed stability of the Gmate Control Solutions was established in k113636.

Stability - Gmate® Test Strips

The claimed stability of the Gmate Test Strips was established in k113636.

Value Assignment - Gmate Control solutions

The Gmate Control Solutions are available at three concentrations L1, 2, and 3. Value assignment for the controls was established under k113636.

d. Detection limit:

The measuring range of the device is 20 - 600 mg/dL. This range was validated by the linearity study (M.1.b).

e. Analytical specificity:

Interference studies were performed by spiking venous blood to two levels of glucose concentrations (approximately 100 and 330 mg/dL). Each of these samples was then divided into five aliquots and spiked with four levels of potential interferent. Each sample was then analyzed five times with the Gmate® SMART meter and the % difference between the mean of the measurements and YSI was calculated. The sponsor defines no significant interference as $\leq \pm$ 10% difference compared to YSI. Results are presented in the table below:

Potential Interfering Substance	Concentration with no Significant Interference (mg/dL)
Acetaminophen	20
Ascorbic Acid	3
Bilirubin	40
Caffeine	50
Cholesterol	500
Dopamine	13
Fructose	50
Galactose	20
Hemoglobin	20
Ibuprofen	40
Lactose	50
L-Dopa	4
Lipoic Acid	50
Maltose	20
Methyldopa	2.5
Salicylic Acid	50
Sucrose	50
Tolbutamide	100
Triglycerides	3000
Urea	500
Uric Acid	20
Xylose	20

The sponsor has the following limitations in their labeling: Reducing substances occurring in normal blood or normal therapeutic concentrations do not significantly affect results. The limiting concentrations of these substances are listed below:

Acetaminophen >20 mg/dL

Bilirubin >40 mg/dL

Ascorbic acid >3 mg/dL

Uric acid >20 mg/dL

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

To assess system accuracy, results from the Gmate® SMART Blood Glucose Monitoring System were compared to a reference method, the YSI 2300. One hundred (100) samples with glucose concentrations ranging from 38 to 432 mg/dL were tested using three test strip lots. Five low concentration samples ranging from 38 to 49 mg/dL were obtained by allowing samples to glycolyze, and five high concentration samples ranging from 402 to 432 mg/dL were obtained by spiking. The results relative to YSI are summarized in the tables below:

For glucose concentrations <75 mg/dL

Site	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Finger	15/ 19 (79%)	19 / 19 (100 %)	19 / 19 (100 %)
Forearm	11/ 19 (58%)	18 / 19 (94.7 %)	19 / 19 (100 %)
Upper Arm	12/ 19 (63%)	19 / 19 (100 %)	19 / 19 (100 %)
Palm	11/ 19 (58%)	18 / 19 (94.7 %)	19 / 19 (100 %)
Thigh	13/ 19 (68%)	18 / 19 (94.7 %)	19 / 19 (100 %)
Calf	12/ 19 (63%)	18 / 19 (94.7 %)	19 / 19 (100 %)

For glucose concentrations ≥ 75 mg/dL

Site	Within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
Finger	70 / 81 (86%)	79 / 81 (98%)	81/ 81 (100%)	81/ 81 (100%)
Forearm	68 / 81 (84%)	75 / 81 (93%)	80 / 81 (99%)	81/ 81 (100%)
Upper Arm	71 / 81 (88%)	79 / 81 (98%)	81/ 81 (100%)	81/ 81 (100%)
Palm	68 / 81 (84%)	77 / 81 (95%)	80 / 81 (99%)	81 / 81 (100%)
Thigh	68 / 81 (84%)	77 / 81 (95%)	80 / 81 (99%)	81 / 81 (100%)
Calf	72/81 (89%)	75 / 81 (93%)	79 / 81 (98%)	81 / 81 (100%)

Linear Regression Analysis:

Comparison	Slope and y-intercept	r^2
Finger	y = 0.993x + 1.912	0.998
Forearm	y = 1.000x + 1.983	0.997
Upper Arm	y = 0.995x +1.902	0.998
Thigh	y = 0.998x + 2.209	0.997
Calf	y = 0.992x + 1.938	0.997
Palm	y = 1.009x + 1.640	0.997

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 Gmate® SMART Blood Glucose Monitoring System in the hands of the intended users the sponsor performed a study with 100 lay user participants, who each collected and analyzed one sample from the finger, forearm, upper arm, hand, thigh and calf samples. Three test strip lots were used in this study. Results were analyzed by comparing blood glucose results from the Gmate® SMART meter obtained by the lay user against the YSI 2300 reference value. All samples were unaltered and concentrations ranged from 58 to 422 mg/dL as measured by YSI. The results are summarized in the tables below:

Lay-user vs. YSI:

For glucose concentrations <75 mg/dL

Site	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Finger	7/10 (70%)	10/10 (100%)	10/10 (100%)
Forearm	5/10 (50%)	9/10 (90%)	10/10 (100%)
Upper Arm	8/10 (80%)	10/10 (100%)	10/10 (100%)
Thigh	7/10 (70%)	9/10 (90%)	10/10 (100%)
Calf	5/10 (50%)	10/10 (100%)	10/10 (100%)
Palm	4/10 (40%)	8/10 (80%)	10/10 (100%)

For glucose concentrations ≥ 75 mg/dL

Site	Within ± 5 %	within ± 10 %	within ± 15 %	Within ± 20 %
Finger	18 / 90 (20 %)	55 / 90 (61 %)	81 / 90 (90 %)	90 / 90 (100 %)
Forearm	22 / 90 (24 %)	68 / 90 (76 %)	89 / 90 (99 %)	90 / 90 (100 %)
Upper Arm	28 / 90 (31 %)	65 / 90 (72 %)	87 / 90 (98 %)	90 / 90 (100 %)
Thigh	23 / 90 (26 %)	67 / 90 (74 %)	88 / 90 (98 %)	90 / 90 (100 %)
Calf	22 / 90 (24 %)	66 / 90 (73 %)	90 / 90 (100 %)	90 / 90 (100 %)
Palm	21 / 90 (23 %)	67 / 90 (74 %)	86 / 90 (96 %)	90 / 90 (100 %)

Linear Regression Analysis:

Comparison	Slope and y-intercept	r^2
Finger	y = 1.003x + 2.257	0.993
Forearm	y = 1.017x – 0.362	0.995
Upper Arm	y = 1.013x + 0.189	0.995
Thigh	y = 1.025x – 0.824	0.996
Calf	y = 1.018x + 0.028	0.995
Palm	y = 1.014x + 1.133	0.995

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   For people without diabetes
   Before eating (FPG) < 100 mg/dL
   Two hours after meals (OGTT) < 140 mg/dL

   Reference: American Diabetes Association (2013). Standards of Medical Care in Diabetes – 2013. Diabetes Care, 36 (Supplement 1): S11-S66.

N. Instrument Name:

Gmate® SMART meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and requires a sample volume of 0.5 µL.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ☒ No ☐

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes ☒ No ☐

2. Software:

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

   Yes ☒ 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:

   This device is intended to be used with capillary whole blood from the finger, forearm, upper arm, thigh, calf, and palm. 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 with a test strip lot-specific code during manufacture. 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:

   Glucose control solutions at three different concentrations are provided for this device. 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. Altitude.

   Venous whole blood samples were adjusted to concentrations of 71, 130, 231, and 371 mg/dL (by the reference method) and were compared to YSI at sea level and 10,000 feet. The study evaluated one test strip lot and ten meters. The results demonstrate acceptable bias and indicate acceptable performance to the claimed altitude of 10,000 ft.

2. Electromagnetic Compatibility (EMC) Testing was evaluated and certified by two third party labs and certificates of compliance were provided.

3. Hematocrit

   The effect of different hematocrit levels on the performance of the Gmate® SMART Blood Glucose Monitoring System was evaluated using venous whole blood samples with hematocrit levels of 20, 30, 40, 50, and 60% spiked with glucose to achieve 5 concentrations at 50, 100, 150, 230, and 330 mg/dL. Each sample was then tested ten times using the Gmate® SMART meter and the values were compared with those obtained from YSI 2300 analyzer. The % biases relative to YSI were acceptable within the claimed hematocrit range of 20 to 60%.

4. Usability / Lay User Questionnaire Results

   A usability study was performed to assess the readability of the labeling 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 it was easy or very easy to use the BGMS.

5. Readability

   A Flesch-Kincaid readability assessment was conducted and the results demonstrated that the Owner's Manual was written at an 8th grade level. Readability for the strip insert, quick reference guide, and control package insert were evaluated during the review of k113636 and determined to be at an 8th grade level or below.

6. Sample Volume

   The sponsor performed a study to verify the test strip minimum sample volume requirement for the Gmate® SMART Blood Glucose Monitoring System. Blood samples were tested at four sample volumes (0.3, 0.5, 0.7, and 1.0 µL) and five glucose concentrations (40, 70, 125, 250, and 450 mg/dL) Glucose values obtained

with the Gmate® SMART were compared to YSI values. Results support the claimed minimum sample volume of 0.5 µL.

7. Temperature and Relative Humidity

   The combined effect of temperature and humidity were evaluated in a chamber where these conditions can be controlled. The sponsor used ten meters and three test strip lots. Whole blood samples with approximate concentrations of 70, 120, 300 mg/dL were tested 30 times under the following conditions:

   10℃, 10% (low temperature, low humidity)

   10℃, 90% (low temperature, high humidity)

   40℃, 10% (high temperature, low humidity)

   40℃, 90% (high temperature, high humidity)

   The results demonstrated that Philosys Gmate SMART produces accurate results over the claimed temperature range of 10-40˚C (50-104˚F) and claimed humidity range of 10-90%.

8. Customer Service Number

   The Customer Service Support is available 24/7, 365 days a year. The toll free phone number is 1-855-464-6283.

9. Infection Control

   This device system is intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter , iPhone 3GS, iPhone 4, iPhone 4S, iPhone 5, iPod touch 4th generation, Pad 1,and iPad 2 by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, CaviWipes with EPA registration # 46781-8.

   Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or in the external materials of the meter, iPhone 3GS, iPhone 4, iPhone 4S, iPhone 5, iPod touch 4th generation, Pad 1, and iPad 2 after 260 cleaning and disinfection cycles designed to simulate 5 years of single-patient device use (to represent 260 cleanings and 260 disinfections). Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

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.