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

A. 510(k) Number:

k151658

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose from the fingertip, forearm, upper arm, palm, thigh, or calf

D. Type of Test:

Quantitative, Amperometric assay, Glucose Oxidase

E. Applicant:

Philosys Co. Ltd.

F. Proprietary and Established Names:

Gmate Origin Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

Product Code	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 Blood Glucose test system	Clinical Chemistry 75
CGA	Class II	21 CFR 862.1345 Glucose Oxidase, Glucose	Clinical Chemistry 75

H. Intended Use:

1. Intended use(s):

See indication(s) for use below

2. Indication(s) for use:

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

The Gmate Origin 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 Gmate Origin Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steadystate times (when glucose is not changing rapidly).

The Gmate Blood Glucose Test Strips are for use with the Gmate Origin Blood Glucose Meter to quantitatively measure 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 over-the-counter use
- Test Strips are designed for use with capillary whole blood samples only.
- Not for screening or diagnosis of diabetes mellitus.
- Use only fresh capillary whole blood, not for use with serum or plasma.
- Not for use on critically ill patients. Test results may be false if the patient is severely in shock, has hypotension, hyperosmolar, or dehydrated.
- Not for neonatal use.
- The blood glucose monitoring system is intended to be used by a single person and should not be shared with any other person.
- Alternate site testing should not be used to calibrate continuous glucose monitoring systems (CGMs).
- Alternate site testing should only be done during steady-state times (when glucose is not changing rapidly).
- Results from alternate site testing should not be used in insulin dose calculation.

4. Special instrument requirements:

Gmate Origin Blood Glucose Meter

I. Device Description:

The Gmate Blood Glucose Monitoring System kit consists of the following components: Gmate Origin Blood Glucose Meter, carrying case, Gmate Origin User Guide and Quick Reference Guide.

Gmate Blood Glucose Test Strips and Gmate Control Solution were previously cleared under k113636 and k131230 respectively and are sold separately. The Gmate control Solutions are available at three concentrations (Level 1, Level 2, and Level 3) and sold separately. Lancets and lancing device are also sold separately.

J. 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		
Item	Candidate Device Gmate Blood Glucose Monitoring System (k151658)	Predicate Device CareSens N Blood Glucose Monitoring System (k083468)
Intended Use	It is intended to be used for quantitative measurement of glucose as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Measuring Range	20 – 600 mg/dL	Same
Sample Type	Capillary whole blood	Same
Measurement Technology	Glucose Oxidase Electrochemical Sensor	Same
Test Time	5 seconds	Same
Calibration Coding	Auto coding	Same
Operating Temperature Range	50 - 104°F (10 – 40 °C)	Same
Operating Relative Humidity Range	10 – 90%	Same
Altitude	10,000 feet (3,048 meters)	Same
Hematocrit Range	20-60%	Same
Minimum Sample Volume	0.50 μL	Same

Differences		
Item	Candidate Device Gmate Blood Glucose Monitoring System (k151658)	Predicate Device CareSens N Blood Glucose Monitoring System (k083468)
Testing sites	Fingertips, forearm, upper arm, palm, thigh, or calf	Fingertips, forearm, palm, thigh or calf
Setting mode	Year, month, day, hour, minute and unit (mg/dL or mmol/L), sound on/off, alarm	Year, month, day, time format, hour, minute, and unit (mg/dL or mmol/L), sound on/off, alarm, and post meal flagging
Memory Capacity	500 blood glucose test results	250 blood glucose test results
Power Source	One 3.0 V lithium battery (disposable, type CR2032)	Two 3.0 V lithium batteries (disposable, typeCR2032)

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

- 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-A3: Method procedure comparison and bias estimation using patient samples; approved guideline.
- CEN 13640: Stability testing of in vitro diagnostic method device
- EN 55011: Mains Terminal Continuous Disturbance Voltage; Radiated electromagnetic field.

L. Test Principle:

The Gmate Origin Blood Glucose Monitoring System is an in vitro diagnostic device intended for the measurement of glucose in capillary blood. The reaction of glucose oxidase in the test strip with glucose in the sample produces an electrical current which is proportional to the amount of glucose in the sample. The meter measures the current and converts it to the corresponding glucose concentration, which is displayed on the meter.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The sponsor performed within-run precision studies using venous whole blood samples consisting of five glucose concentration ranges (30-50, 51-110, 111-150, 151-200, and 251-400 mg/dL). Samples were tested using three lots of strips and 10 meters per test strip lot. Each of the five samples was tested in replicates of fifty by two operators using three lots of test strips and twenty meters for a total of 100 results per strip lot per glucose level. Results are summarized below:

Within-run precision:

Glucose Level (mg/dL)	n	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
30-50	100	1	46.1	3.1	6.8
	100	2	45.7	4.2	4.1
	100	3	46.4	3.3	7.1
51-110	100	1	103.1	4.2	4.1
	100	2	103.2	4.2	4.1
	100	3	103.7	4.2	4.0
111-150	100	1	124.0	3.9	3.1
	100	2	123.8	3.8	3.1
	100	3	123.7	3.7	3.0
151-250	100	1	230.3	6.3	2.7
	100	2	228.9	5.6	2.5
	100	3	230.3	6.2	2.7
251-400	100	1	331.0	6.0	1.9
	100	2	329.7	7.5	2.3
	100	3	329.8	6.2	1.9

Intermediate precision was evaluated using three lots of test strips and twenty meters. Glucose control solutions in three concentration ranges (35-65, 75-125, and 225-375 mg/dL) were measured 3 times a day, with each of three test strip lots per day, for each of the twenty meters for 20 days for a total of 120 results per level per test strip lot. Results are summarized below:

Intermediate precision:

Control Level (mg/dL)	n	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
35-65	120	1	45.5	0.8	1.8
	120	2	45.6	0.7	1.5
	120	3	45.6	0.8	1.5
75-125	120	1	105.3	0.5	0.5
	120	2	105.5	0.7	0.6
	120	3	105.5	0.7	0.6
225-375	120	1	311.0	1.5	0.5
	120	2	311.0	1.5	0.5
	120	3	310.6	1.2	0.4

b. Linearity/assay reportable range:

Linearity was evaluated testing 14 serially diluted venous whole blood samples to achieve target concentrations as follows: 7.0, 16.0, 24.0, 42.0, 64.0, 73.0, 83.0, 162.0, 241.0, 319.0, 401.0, 470.0, 550.0, and 630.0 mg/dL as measured by the YSI reference method. Each glucose level was measured in replicates of five with each of the 3 test

strip lots and the values from the Gmate Origin meter were compared with those obtained from the reference method (YSI). Results from regression analysis:

Test Strip Lot 1: $y = 1.000x - 0.812$; $R^2 = 0.999$
Test Strip Lot 2: $y = 1.002x - 0.212$; $R^2 = 0.999$
Test Strip Lot 3: $y = 0.997x + 1.48$; $R^2 = 0.999$

The results of the study support the sponsors claimed glucose measuring range of 20-600 mg/dL. Studies were provided demonstrating that the meter displays "Low" when glucose values below 20 mg/dL are tested, and "Hi" with glucose values over 600 mg/dL are tested.

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

Traceability

The Gmate Origin Blood Glucose Monitoring System is traceable to NIST SRM 917b. The method comparison study was performed using the candidate device and YSI as the reference method (see Section 2.a.)

Test Strip Stability

Test strip stability was established in k113636 to support the sponsor's claim of 24 month shelf life and 3 month open vial stability when stored at 36°F to 90°F (2°C to 32°C) and relative humidity of 10% to 90%.

Control Solution Value Assignment and Stability

Value assignment and stability were established under k113636. The control solution stability protocols and acceptance criteria provided in k113636 support the sponsor's claim of a 24 month shelf life and a 3 month open vial stability when stored at 4-30°C

d. *Detection limit:*

See linearity study in Section M.1.b above.

e. *Analytical specificity:*
To assess potential interference, the sponsor tested samples with 2 levels of glucose concentrations of approximately 100 and 330 mg/dL by spiking with potentially interfering substances at 4 different concentrations. Each sample was analyzed 5 times with the Gmate Origin meter. The test results of the spiked samples were compared with results measured from control samples without potential interfering substances. The percent difference between the test and control samples was calculated and the sponsor defined no significant interference as ≤±10%. Results are presented in the table below:

Potential Interfering Substance	Highest Concentration at which no significant interference was observed (mg/dL)
Acetaminophen	20
Ascorbic acid	3
Dopamine	13
Ibuprofen	40
L-Dopa	4
Methyl Dopa	2.5
Salicylic Acid	50
Tolbutamide	100
Total Bilirubin	40
Cholesterol	500
Creatine	30
Triglycerides	3000
Uric Acid	50
Maltose	500
Xylose	20
Galactose	20
Lactose	50
Urea	500
Caffeine	50
Fructose	50
Lipoic acid	50
Sucrose	50
Hemoglobin	20
Gentisic acid	50
Tolazamide	200
Glutathione	12.3
Sodium	3150
Heparin	2.14

Based on these results, the sponsor has the following limitations in the labeling:
If you are taking acetaminophen (e.g. Tylenol, etc.) or Vitamin C (ascorbic acid) at a higher than therapeutic doses (>20 mg/dL acetaminophen or >3 mg/dL ascorbic acid) you may get inaccurate results using this meter.

Cholesterol levels greater than 500 mg/dL, or triglyceride levels greater than 3,000 mg/dL may produce elevated readings.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

To assess system accuracy, results from the Gmate Origin Blood Glucose Monitoring System were compared to an established glucose reference method, the YSI 2300 STAT. Three hundred (300) capillary blood samples from the fingertip, palm, forearm, upper arm, thigh and calf (300 samples from each site) were tested by trained operators using 10 meters and 3 lots of test strips. The candidate results were compared to results obtained by the YSI 2300 method. The glucose concentrations of the total tested samples ranged from 34.4 mg/dL to 450 mg/dL as measured by the YSI2 300 reference method. To obtain glucose levels of less than 50 mg/dL and greater than 400 mg/dL samples were allowed to glycolyze or were spiked. The results from the YSI 2300 STAT vs. Gmate Origin Blood Glucose System are summarized in the tables below:

Fingertip: for blood glucose concentrations <75mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
55/55 (100%)	55/55 (100%)	55/55 (100%)

Fingertip: System Accuracy for blood glucose concentration ≥75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
208/245 (85%)	239/245 (98%)	245/245 (100%)	245/245 (100%)

Fingertip Linear regression: y=0.9807x+ 3.245; R^2 = 0.999

Palm: System Accuracy for blood glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
55/55 (100%)	55/55 (100%)	55/55 (100%)

Palm: System Accuracy for blood glucose concentration ≥75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
236/245 (96%)	243/245 (99%)	245/245 (100.0%)	245/245 (100%)

Palm Linear regression: y=0.9848x+ 2.087; R^2= 0.999

Forearm: System Accuracy for blood glucose concentration <75mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
55/55 (100%)	55/55 (100%)	55/55 (100%)

Forearm: System Accuracy for blood glucose concentration ≥75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
240/245 (98%)	245/245 (100%)	245/245 (100%)	245/245 (100%)

Forearm Linear regression: y=0.9932x+ 1.171; R^2= 0.998

Upper arm: System Accuracy for blood glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
55/55 (100%)	55/55 (100%)	55/55 (100%)

Upper arm: System Accuracy for blood glucose concentration ≥75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
238/245 (97%)	245/245 (100%)	245/245 (100.0%)	245/245 (100%)

Upper arm Linear regression: y=0.9929x+ 2.371; R^2= 0.999

Thigh: System Accuracy for blood glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
53/55 (96%)	55/55 (100%)	55/55 (100%)

Thigh: System Accuracy for blood glucose concentration ≥75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ±20%
213/245 (87%)	245/245 (100%)	245/245 (100%)	245/245 (100%)

Thigh Linear regression: y=0.980 x+ 2.1334; R^2= 0.998

Calf: System Accuracy for blood glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
55/55 (100%)	55/55 (100%)	55/55 (100%)

Calf: System Accuracy for blood glucose concentration ≥75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
213/245 (87%)	245/245 (100%)	245/245 (100%)	245/245 (100%)

Calf Linear regression: y=0.980 x+ 2.1334; 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 Gmate Origin Blood Glucose Monitoring System in the hands of the intended users, a study was conducted with 100 lay-user participants, with varying demographics, age, sex and education level. The study participants were provided with the User's Manual in English and collected and analyzed one sample from the finger, forearm, upper arm, palm, thigh and calf without additional instruction

or assistance. A technician collected additional samples from each participant for measurement on an established laboratory reference method (YSI 2300 analyzer). Results from participants with the candidate device were compared to results obtained by technicians with the reference method. The range of glucose values tested was 34.8 - 443 mg/dL as measured by the YSI 2300 analyzer. The results obtained by participants using the candidate meter relative to the reference method (YSI) are summarized below:

Glucose concentrations <75 mg/dL

Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Finger	6/7 (86%)	7/7 (100%)	7/7 (100%)
Forearm	7/7 (100%)	7/7 (100%)	7/7 (100%)
Upper arm	6/7 (86%)	7/7 (100%)	7/7 (100%)
Thigh	5/7 (71%)	7/7 (100 %)	7/7 (100%)
Calf	6/7 (86%)	7/7 (100%)	7/7 (100%)
Palm	4/7 (57%)	7/7 (100%)	7/7 (100%)

Glucose concentrations ≥75 mg/dL

Site	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Fingertip	59/93 (63%)	87/93(94%)	93/93 (100%)	93/93 (100%)
Forearm	60/93 (65%)	87/93 (94%)	93/93 (100%)	93/93 (100%)
Upper arm	75/93 (81%)	93/93 (100%)	93/93 (100%)	93/93 (100%)
Thigh	50/93 (54%)	86/93 (92%)	92/93 (99%)	93/93 (100%)
Calf	53/93 (57%)	89/93 (96%)	93/93 (100%)	93/93 (100%)
Palm	54/93 (58%)	86/93 (92%)	93/93 (100%)	93/93 (100%)

Linear regression analysis:

Comparison	Slope and y-intercept	R^2
Fingertip	y=1.0272 x + 6.38	0.996
Forearm	y=1.0458x + 1.01	0.996
Upper arm	y=1.061x -0.139	0.996
Thigh	y=1.0462x + 1.99	0.997
Calf	y=1.0446x + 4.43	0.996
Palm	y=1.0388x + 4.55	0.996

Usability / Lay user Questionnaire Results:
The lay users completed a questionnaire regarding the clarity of the instructions and the ease of use of the device and demonstrated that the device was easy to use.

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

Expected glucose values for persons without diabetes:

Status	Range (mg/dL)
Fasting	<100 mg/dL
Two hours after meals	<140 mg/dL

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

N. Instrument Name:

Gmate Origin Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and requires a sample volume of 0.50 µL.

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 test is intended to be used with capillary whole blood from the fingertip, palm, upper arm, forearm, thigh, or calf. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   There is no calibration required for the blood glucose meter by the user. The meter is automatically coded. 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:

   Three levels of aqueous glucose control solutions are available with this system, Level 1, Level 2 and Level 3. These solutions are available for purchase 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 bottle label. The user is cautioned not to use the meter if the control result falls outside these ranges. The meter automatically distinguishes control solution from blood and marks control solution tests with an icon and excludes them from average calculations

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

1. Sample volume Study:
   The sponsor performed a study to verify the test strip minimum sample volume requirement for the Gmate Origin Blood Glucose Monitoring System. Blood samples were tested at a four sample volumes (0.3, 0.5, 0.7, and 1.0 µL) and five glucose concentrations (50, 70, 120, 230, and 430 mg/dL). Glucose values obtained with the Gmate Origin system were compared to YSI values. Results support the claimed minimum sample volume of 0.50 µL.

2. Altitude Study:
   A study was conducted to evaluate the effect of altitude on the Gmate Origin Blood Glucose Monitoring System. Venous whole blood samples adjusted to concentrations of 70, 130, 230, and 380 mg/dL were evaluated using a hyperbaric chamber at three altitude levels (sea level at 0 feet, 3000, 6000, and 10,000 feet). Results were compared to YSI values. The results demonstrate acceptable bias to YSI to support the claims in the labeling that altitudes up to 10,000 feet have no significant effect on blood glucose measurements from the Gmate Origin Blood Glucose Monitoring System.

3. Hematocrit Study:
   The effect of different hematocrit levels on the performance of the Gmate Origin Blood Glucose Monitoring System was evaluated using venous whole blood at five glucose concentrations (50, 100, 150, 230, and 330 mg/dL) and five hematocrit levels (20, 30, 40, 50, and 60%). Each sample was measured in ten replicates and values were compared to those measured with an established laboratory reference method (YSI 2300 analyzer). Results relative to YSI were acceptable and support the sponsor's hematocrit claim of 20-60%.

4. Temperature and Relative Humidity:
   The effect of temperature and relative humidity on the Gmate Origin Blood Glucose Monitoring System was evaluated using ten meters and three test strip lots. Whole blood samples with approximate glucose concentrations of 70, 120, and 325 mg/dL were tested in triplicate on each of the ten meters. The Gmate Origin Blood Glucose Monitoring System was evaluated under the following conditions: 10°C, 10% RH (low temperature, low humidity); 10°C, 90% RH (low temperature, high humidity); 40°C, 10% RH (high temperature, low humidity); and 40°C, 90% RH (high temperature, high humidity). The results of the Gmate Origin Blood Glucose Monitoring System relative to YSI support the claimed operating conditions of 10-40°C (50-104°F) and 10-90% relative humidity.

5. Readability Assessment:
   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 test strip insert was evaluated during the review for k113636 and was determined to be at an 8th grade level or below.

6. Infection Control/Robustness Studies:
   The device is intended for a single-patient use only. Disinfection efficacy studies were performed on the external materials of the blood glucose meter by an outside commercial testing laboratory demonstrating complete inactivation of Hepatitis B virus with the chosen disinfectant, CaviWipes with EPA registration # 46781-8. Robustness studies were also performed by the sponsor to demonstrate that there was no change in performance or in the external materials of the meter after 260 cleaning and disinfection cycles designed to simulate 5 years of single-patient devise use (260 cleanings and 260 disinfections). Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

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

8. Software validation:
   Software validation and verification has been reviewed and the information provided was deemed to be adequate.

9. EMC Testing:
   The sponsor provided appropriate documentation certifying that electromagnetic testing (EMC) has been performed and the Gmate Origin Blood Glucose Monitoring System was found to be compliant.

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.