DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 1, 2015

PHILOSYS, INC.
LINDA CHAN
MANAGER
304 PARK AVENUE SOUTH, SUITE 218
NEW YORK NY 10016

Re: K151658
Trade/Device Name: Gmate® Origin Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: October 14, 2015
Received: October 15, 2015

Dear Linda Chan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151658

Device Name

Gmate® Origin Blood Glucose Monitoring System

Indications for Use *(Describe)*

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 Blood 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. 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® 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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

(As required by 21.CFR.807.92)

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Email: lchan@usdiagnostics.net

Date Summary, Prepared:

June 16, 2015

Device Name:

Propriety Name:
Gmate® Origin Blood Glucose Monitoring System

Model Number: PG-310

Common Name: Blood Glucose Test System, Blood Glucose Monitoring System

Classification Name: Blood Glucose, Test, System, Glucose Oxidase, over the counter

Product Code	Classification	Regulation Section	Panel
CGA	II	21 CFR 862.1345	Chemistry (75)
NBW	II	21 CFR 862.1345	Chemistry (75)

Predicate Device:

We claim substantial equivalence to:
1) K083468 – I-SENS, Inc. CareSens N Blood Glucose Monitoring System

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510(k) SUMMARY

(As required by 21.CFR.807.92)

Device Description:

The Gmate® Origin Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood. The Gmate® Origin 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® Origin Blood Glucose Monitoring System consists of a glucose meter, test strips, and one control material (additional levels of control material are available upon request). The Gmate® Origin Blood Glucose Monitoring System do not require coding or calibration and uses 1 CR2032 (Lithium Ion Battery). Insert the test strip into the meter, apply the blood or control solution to the strip and the meter will begin the 5 seconds countdown to display the test result.

The test principle is:
This device is an in vitro diagnostic only product intended for the measurement of glucose concentration in human blood. The principle of the test relies upon a specific type of glucose in the blood sample, the glucose oxidase that reacts to electrodes in the test strip. The test strip employs an electrochemical signal generating an electrical current that will stimulate a chemical reaction. The meter measures the current and calculates your blood glucose level.

Intended 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 Blood 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. 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® 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.

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510(k) SUMMARY

(As required by 21.CFR.807.92)

Comparison to Predicate Device:

The indications for use and the scientific technology of the Gmate® Origin Blood Glucose Monitoring System and the predicate device are similar. The assay method, detection method, enzyme, mediator, test time, calibration, glucose unit, and battery life of the Gmate® Origin system are exactly the same as the predicate device. There are few items of the specifications such as test range, storage conditions, temperature, size, weight and modes that will differ.

As shown in the summary performance testing data of the clinical and non-clinical comparison, it demonstrated that those differences do not raise issues of safety and effectiveness. Therefore, based on the information provided in this Premarket notification, we conclude the Gmate® Origin Blood Glucose Monitoring System is safe, effective, and substantially equivalent to the predicate device as described herein.

The Gmate® Control Solution has been previous approved under K131230.

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Performance Data:

Non-clinical and clinical tests for the Gmate® Origin Blood Glucose Monitoring System were performed in accordance with FDA Guidance Documents and CLSI reference standards.

The clinical performance evaluation testing included system accuracy, user performance, and alternative-site blood glucose measurement.

The non-clinical performance evaluation testing included precision, linearity, interference, hematocrit, altitude, and temperature/humidity. These evaluations were conducted to establish the performance, the functionality and the reliability characteristics of the Gmate® Origin System.

The evaluations of the Gmate® Origin System was assessed by comparing blood glucose results obtained by patients with those obtained using the YSI 2300 Glucose Analyzer, a laboratory instrument. Glucose levels were measured on 100 persons with diabetes and healthcare professionals at a clinic center.

No adverse events occurred during the studies. The results demonstrated that the Gmate® Origin met all the reliability requirements and performance claims.

Based on the comparisons completed of the clinical and non-clinical tests performed, the devices passed all of the tests based on pre-determined Pass/Fail Criteria.

Conclusion:

The Gmate® Origin Blood Glucose Monitoring System is safe and effective and substantially equivalent to K083468 – I-SENS, Inc. CareSens N Blood Glucose Monitoring System.