August 25, 2022

Apex Biotechnology Corp.
Lisa Liu
Manager of Quality Assurance Department
No. 7, Li-Hsin Rd. V, Hsinchu Science Park
Hsinchu, 30078
Taiwan

Re: K212140
Trade/Device Name: GlucoSure Link Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: May 13, 2022
Received: May 16, 2022

Dear Lisa Liu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Paula Caposino, Ph.D.
Acting Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212140

Device Name
GlucoSure Link Blood Glucose Monitoring System

Indications for Use *(Describe)*
The GlucoSure Link Blood Glucose Monitoring System is comprised of GlucoSure Link Blood Glucose Meter and GlucoSure Link Blood Glucose Test Strips.
The GlucoSure Link Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). This system is intended for self-testing (outside the body, or In Vitro Diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of your diabetes control and should only be used by a single patient and not be shared. It is not intended to be used for the diagnosis or screening of diabetes or for use on neonates.

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

510(k) Number:	k212140
Submitter:	Apex Biotechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN)
Contact Person:	Lisa Liu Manager of Quality Assurance Division Apex Biotechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN) email: lisaliu@apexbio.com Phone: 011-886-3-5641952 FAX: 011-886-3-5678021
Date Prepared:	09/13/2020
Trade Names:	GlucoSure Link Blood Glucose Monitoring System
Classification:	Glucose test system, 21 CFR 862.1345, Class II
Product Codes:	NBW
Predicate Devices:	AutoSure Voice II Blood Glucose System (k102037)
Device Description:	The GlucoSure Link blood glucose monitoring system consists of the GlucoSure Link meter, GlucoSure Link Blood Glucose Test Strips and Contrex Plus glucose control solution. It is used for testing of blood glucose by self-testers at home. The GlucoSure Link Blood Glucose Test Strips and Contrex Plus glucose control solution are purchased separately. The modified device of GlucoSure Link glucose meter is derived from the existing device of AutoSure Voice II meter and the modified device contain the Bluetooth function to transfer glucose results to the mobile device and removed the voice Feature. The glucose test strips and glucose control solution utilized in the GlucoSure Link Blood Glucose Monitoring System are the same as the AutoSure glucose test strips and Contrex Plus Glucose Control Solution, previously cleared in k102037.

	The meter materials of GlucoSure Link glucose meter are the same as the AutoSure Voice II meter. Therefore, the disinfection performance (robustness of meter to multiple cleanings and disinfections) was previously cleared in k150396.
Intended Use:	The GlucoSure Link Blood Glucose Monitoring System is comprised of GlucoSure Link Blood Glucose Meter and GlucoSure Link Blood Glucose Test Strips. The GlucoSure Link Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). This system is intended for self-testing (outside the body, or In Vitro Diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of your diabetes control and should only be used by a single patient and not be shared. It is not intended to be used for the diagnosis or screening of diabetes or for use on neonates.
Comparison of Technological Characteristics:	The GlucoSure Link Blood Glucose meter uses the same test strip and test algorithm as the predicate. The changes was for • Voice Feature was removed. • Bluetooth connectivity was added to the meter. • Added error message Err5:Bluetooth failure, Err6:During bonding procedure, authorization by meter fails, Err7:During data transmission via BLE, a strip was inserted Err8:If meter is master mode and when BLE disconnection between meter and cell-phone happens during transmission procedure, meter shall show error message • Change in name from AutoSure Voice II Blood Glucose Monitoring System to GlucoSure Link Blood Glucose Monitoring System. • The GlucoSure Link Blood Glucose Monitoring System shares identical glucose test strips with AutoSure Voice II Blood Glucose Monitoring System, but only change in brand name from AutoSure Blood Glucose Test Strips to GlucoSure Link Blood Glucose Test Strips.

Non-Clinical Testing:	Testing was conducted as follows: EMC and Electrical Safety, Software verification and validation including cybersecurity management, linearity, precision, short sample detection, intermittent sampling, sample perturbation, temperature and humidity testing and results demonstrate substantial equivalence to the predicate system.
Clinical Testing	Method comparison and user studies for glucose were conducted with home users, including evaluation of ease of use and ease of understanding of the user manual. Results demonstrate substantial equivalence to the predicate system. Accuracy at extreme glucose values were also evaluated.
Conclusion:	Clinical and analytical testing demonstrated that the GlucoSure Link Blood Glucose Monitoring System perform in a substantially equivalent manner to that of the predicate. We conclude that the GlucoSure Link Blood Glucose Monitoring System is substantially equivalent to the predicate system.