September 15, 2021

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

Re: K202885
Trade/Device Name: GlucoSure HT Plus Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: November 9, 2020
Received: November 12, 2020

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,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K202885

Device Name
GlucoSure HT Plus Blood Glucose Monitoring System

Indications for Use *(Describe)*
GlucoSure HT Plus Blood Glucose Monitoring System is intended to quantitatively measure blood glucose in fresh capillary whole blood drawn from fingertips, palm, or forearm. Alternative site testing for glucose test should be performed only during steady-state (when glucose is not changing rapidly). It is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control and should only be used by a single patient and it should not be shared. It is not intended for diagnosis or screening of diabetes or for neonatal use.

The GlucoSure HT Blood Glucose Test Strips are to be used with the GlucoSure HT Plus Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510(k) number	K202885
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	November 10, 2020
Trade Names	GlucoSure HT Plus Blood Glucose Monitoring System
Classification	Glucose test system, 21 CFR 862.1345, Class II
Product Codes	NBW
Predicate Devices	BGM009 Plus Blood Glucose System (k170267)
Device Description	The GlucoSure HT Plus blood glucose monitoring system consists of the GlucoSure HT Plus meter and GlucoSure HT Test Strips. It is used for testing of blood glucose by self-testers at home.
Intended Use	GlucoSure HT Plus Blood Glucose Monitoring System is intended to quantitatively measure blood glucose in fresh capillary whole blood drawn from fingertips, palm, or forearm. Alternative site testing for glucose test should be performed only during steady-state (when glucose is not changing rapidly). It is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control and should only be used by a single patient and it should not be shared. It is not intended for diagnosis or screening of diabetes or for neonatal use. The GlucoSure HT Blood Glucose Test Strips are to be used with the GlucoSure HT Plus Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm.

510(k) Summary (Continued)

Comparison of Technological Characteristics	The GlucoSure HT Plus Blood Glucose meter uses the same test strip and test algorithm as the predicate. The changes were for • Dimensions of the meter were changed from 93x58x20.5 (mm) to 96x58x16 (mm) • Meter was changed to add the strip ejection button. • Power source was changed from two AAA 1.5V battery to two 3.0 V lithium battery (CR2032) • LCD change: size change, add new icons and add back light • PCB circuit change according to changed LCD and battery requirement. • Increase glucose memory capacity from 300 to 500 memories and add 1, 60, 90 days' average reading. • The user interface was added reading tag (before meal, after meal, excise, and event) and hypo/hyper setting for glucose reading. • Error code change: • Remove error code "Premature sample application" • Used Test Strip Warning change from Error 3 to Error 2 • Not Enough Sample Warning change from Error 4 to Error 3 • Changing the meaning of Error 4 from "Not Enough Sample Warning" to "Remove test strip during count down" • Change in name from BGM009 Plus Blood Glucose Monitoring System to GlucoSure HT Plus Blood Glucose Monitoring System • The GlucoSure HT Plus Blood Glucose Monitoring System shares identical glucose test strips with BGM009 Plus Blood Glucose Monitoring System, but only change in brand name from BGM009 Blood Glucose Test Strips to GlucoSure HT Blood Glucose Test Strips. Besides, the GlucoSure HT Blood Glucose test strip add single aluminum foil package.
Non-Clinical Testing	Software verification and validation were done. Battery life test, aluminum foil stability test were also done, and results demonstrate substantial equivalence to the predicate system.
Clinical Testing	User studies for glucose was 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.
Conclusion	Clinical and analytical testing demonstrated that the GlucoSure HT Plus Blood Glucose Monitoring System perform in a substantially equivalent manner to that of the predicate. We conclude that the GlucoSure HT Plus Blood Glucose Monitoring System is substantially equivalent to the predicate system.