April 6, 2022

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

Re: K202534
Trade/Device Name: MTM301 Blood Glucose and Ketone Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, JIN
Dated: December 30, 2021
Received: January 6, 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,

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)*
K202534

Device Name
MTM301 Blood Glucose and Ketone Monitoring System

Indications for Use *(Describe)*
MTM301 Blood Glucose and Ketone Monitoring System: MTM301 Blood Glucose and Ketone Monitoring System is comprised of the MTM301 Blood Glucose and Ketone Meter, the MTM301 Blood Glucose Test Strips, and the MTM301 Blood Ketone test strips.
The MTM301 Blood Glucose and Ketone Monitoring System is intended to quantitatively measure blood glucose or blood ketone in fresh capillary whole blood drawn from fingertips. The system 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.

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	K202534
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
Trade Names:	MTM301 Blood Glucose and Ketone Monitoring System
Classification:	Blood glucose test system, over the counter, 21 CFR 862.1345, Class II Ketones (nonquantitative) test system, 21 CFR 862.1435, Class I, meets the limitation of exemption 21 CFR 862.9(c)(5).
Product Codes:	NBW、JIN
Predicate Devices:	Nova Max Plus Blood Glucose and β-Ketone Monitoring System (k091547)
Device Description:	The MTM301 Blood Glucose and Ketone Monitoring System consists of the MTM301 Blood Glucose and Ketone Meter, MTM301 Blood Glucose test strips, MTM301 Blood Ketone test strips, MTM301 Glucose Control Solution (Level 1, Level 2), and MTM301 ketone control solution (Level 1 and Level 2). The system is for self-testing of blood glucose and blood ketone. The MTM301 Blood Glucose test strips, MTM301 Blood Ketone test strips, MTM301 Glucose Control Solution, and MTM301 ketone control solution are purchased separately. The glucose test strips utilized in the MTM301 Blood Glucose and Ketone Monitoring System are the same as the BGM009 glucose test strips previously cleared in k170267； The ketone test strips are the same as the KET-1 Blood Ketone test strips, previously cleared in k182593.

Intended Use:	MTM301 Blood Glucose and Ketone Monitoring System: MTM301 Blood Glucose and Ketone Monitoring System is comprised of the MTM301 Blood Glucose and Ketone Meter, the MTM301 Blood Glucose Test Strips, and the MTM301 Blood Ketone test strips. The MTM301 Blood Glucose and Ketone Monitoring System is intended to quantitatively measure blood glucose or blood ketone in fresh capillary whole blood drawn from fingertips. The system 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.
Comparison of Technological Characteristics:	Glucose measurement is based on electrochemical biosensor technology using the enzyme Glucose Oxidase (GOD). The MTM301 Blood Glucose test strips contains the enzyme, GOD, when blood flow into the reaction zone, the enzyme reacts with glucose in blood and produces electrical current. The MTM301 Blood Glucose and Ketone meter measures the current and shows the test result in 5 seconds. The technological characteristics of MTM301 Blood Glucose and Ketone Monitoring System are substantially equivalent to the predicate system (k091547). Ketone measurement is based on electrochemical biosensor technology using the enzyme ß -hydroxybutyrate dehydrogenase (HBDH). The MTM301 Blood Ketone test strips contains the enzyme, HBDH, when blood flow into the reaction zone, the enzyme reacts with ß-Hydroxybutyrate (ß-ketone) in blood and produces electrical current. The MTM301 Blood Glucose and Ketone meter measures the current and shows the test result in 8 seconds. The technological characteristics of MTM301 Blood Glucose and Ketone Monitoring System are substantially equivalent to the predicate system (k091547).
Non-Clinical Testing:	Testing was conducted as follows: disinfection performance (robustness of meter to multiple cleanings and disinfections), software verification and validation, linearity study, precision testing, repeatability testing, temperature and humidity testing, intermittent sampling testing, sample perturbation testing and stability test. Results demonstrate substantial equivalence to the predicate system.

Clinical Testing	Accuracy studies for glucose and ketone 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.
Conclusion:	Clinical and analytical testing demonstrated that the MTM301 Blood Glucose and Ketone Monitoring System perform in a substantially equivalent manner to that of the predicate. We conclude that the MTM301 Blood Glucose and Ketone Monitoring System is substantially equivalent to the predicate system.