April 4, 2025

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

Re: K242209
Trade/Device Name: UASure II Blood Uric Acid Monitoring System
Regulation Number: 21 CFR 862.1775
Regulation Name: Uric Acid Test System
Regulatory Class: Class I, reserved
Product Code: PTC
Dated: February 25, 2025
Received: February 25, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 V. Caposino -S

Paula Caposino, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242209

Device Name
UASure II Blood Uric Acid Monitoring System

Indications for Use *(Describe)*
This UASure II Blood Uric Acid Monitoring System measures blood uric acid levels in fresh capillary whole blood drawn from fingertips. It is intended for single-patient home use by prescription and should not be shared. It is intended for self-testing outside the body (in vitro diagnostic use) by people with gout as an aid to monitor the effectiveness of uric acid control.
The UASure II Blood Uric Acid Monitoring System helps track uric acid levels but does not diagnose Hyperuricemia or Gout. Do not change medications based on test results without talking to a doctor.
The UASure II Blood Uric Acid Monitoring System includes the UASure II Meter, UASure II Blood Uric Acid Test Strips and UASure II Uric Acid Control Solution.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

510(k) Number:	K242209
Submitter:	Apex Biotechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 TAIWAN
Contact Person:	Lisa Liu Manager of Quality Assurance Division Apex Biotechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 TAIWAN email: lisaliu@apexbio.com Phone: 011-886-3-5641952 FAX: 011-886-3-5678021
Date Prepared:	07/24/2024
Trade Names:	UASure II Blood Uric Acid Monitoring System
Medical Specialty	Clinical Chemistry
Regulation Citation	21 CFR 862.1775 Uric acid test system
Classification:	Class I, reserved (for PTC)
Product Codes:	PTC
Predicate Devices:	Nova Max Uric Acid Monitoring System (K160990)
Device Description:	The UASure II Blood Uric Acid Monitoring System consists of the UASure II Blood Uric Acid Meter, UASure II Blood Uric Acid Test Strip and UASure II Uric Acid control solution. It is used for testing of blood uric acid by self-testers at home use by prescription only. The UASure II Blood Uric Acid Test Strip and UASure II Uric Acid control solution are purchased separately.
Intended Use:	This UASure II Blood Uric Acid Monitoring System measures blood uric acid levels in fresh capillary whole blood drawn from fingertips. It is intended for single-patient home use by prescription and should not be shared. It is intended for self-testing outside the body (in vitro diagnostic

	use) by people with gout as an aid to monitor the effectiveness of uric acid control. The UASure II Blood Uric Acid Monitoring System helps track uric acid levels but does not diagnose Hyperuricemia or Gout. Do not change medications based on test results without talking to a doctor. The UASure II Blood Uric Acid Monitoring System includes the UASure II Meter, UASure II Blood Uric Acid Test Strips and UASure II Uric Acid Control Solution.
Technological Characteristics:	The Methodology for UASure II Blood Uric Acid Monitoring System is Amperometry. The uric acid in blood was oxidized and generate current that can be quantified on the electrode. The current generated at the electrode is proportional to the uric acid concentration of the sample. By measuring the generated current, the concentration of Uric Acid in the sample is determined.
Non-Clinical Testing:	Testing was conducted as follows: EMC and Electrical Safety, disinfection performance (robustness of meter to multiple cleanings and disinfections), software verification and validation, drop test, USB plug pull out test, linearity testing with validation of Lo/Hi detection, detection Limits Study, temperature and humidity testing, sample volume verification, precision testing, repeatability testing, Stability testing, interferences testing, altitude testing, hematocrit performance testing, results demonstrate substantial equivalence to the current methods for uric acid measurements.
Clinical Testing	An accuracy study was conducted with home users using finger capillary whole blood. Results demonstrate substantial equivalence to the predicate system.
Conclusion:	Clinical and analytical testing demonstrated that the UASure II Blood Uric Acid Monitoring System perform in a substantially equivalent manner to that of the predicate. We conclude that the UASure II Blood Uric Acid Monitoring System is substantially equivalent to the predicate system.