January 30, 2025

Guangdong Transtek Medical Electronics Co., Ltd.
Mark Qian
Quality Director
Zone A, No. 105, Dongli Road, Torch Development District
Zhongshan, Guangdong 528437
China

Re: K243060
Trade/Device Name: TeleRPM Gen2 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: December 27, 2024
Received: December 27, 2024

Dear Mark Qian:

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,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
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)*
k243060

Device Name
TeleRPM Gen2 Blood Glucose Monitoring System

Indications for Use *(Describe)*
TeleRPM Gen2 Blood Glucose Monitoring System is comprised of the TeleRPM Gen2 Blood Glucose Meter and the TeleRPM Blood Glucose Test Strips. TeleRPM Gen2 Blood Glucose Monitoring System is intended to quantitatively measure the glucose concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by persons with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for neonatal use or for the diagnosis of or screening for diabetes. This system is intended for self-testing outside the body (in vitro diagnostic use), and should only be used by a single person and should not be shared.

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.

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with 21 CFR 807.92.

The assigned 510(k) number is k243060

1. Submitter's Information:

1.1 Submitter's Name, Address and Telephone Number

Name: Guangdong Transtek Medical Electronics Co., Ltd.

Address: Zone A, No.105, Dongli Road, Torch Development District,
Zhongshan, 528437, Guangdong, China.

Telephone: + 86 0760 8828 2982

1.2 Contact Person:

Name: Mark Qian

Position: Quality Director

Email: mark.qian@vivachekbio.com

1.3 Date Updated for Summary

Jan 29, 2025

2. Devices Name

2.1 Proprietary Name:

TeleRPM Gen2 Blood Glucose Monitoring System

2.2 Common Name:

Glucose Test System

2.3 Classification Name:

Classification Name: Glucose Test System

Regulation Number: 21 CFR 862.1345

Regulatory Class: Class II

Product Code: NBW

2.4 Predicate (Legally Marketed) Device

Predicate Name: VivaChek™ Link Plus Blood Glucose Monitoring System.

510(k) Number: k233058.

Applicant: VivaChek Biotech (Hangzhou) Co., Ltd.

No reference device is used in this submission.

3. Device Description

TeleRPM Gen2 Blood Glucose Monitoring System consists of TeleRPM Gen2 Blood Glucose Meter and the TeleRPM Blood Glucose Test Strips.

TeleRPM Control Solution, TeleRPM Lancing Device, TeleRPM Lancets are required for use but not included in meter box or test strips box and should be purchased separately. The TeleRPM Control Solution is for use with the above meter and test strip as a quality control check to verify that the meter and test strip are working together properly, and that the test is performing correctly. TeleRPM Lancing Device and TeleRPM Lancets are used for puncturing fingertip and then user can perform glucose test with blood sample.

TeleRPM Gen2 Blood Glucose Monitoring System is designed to quantitatively measure the glucose concentration in fresh capillary whole blood from the fingertip. The glucose measurement is achieved by using the amperometric detection method. The test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the test strip. The blood sample is pulled into the tip of the test strip through capillary action. Glucose in the sample reacts with glucose oxidase and the mediator. Electrons are generated, producing a current that is positive correlation to the glucose concentration in the sample. After the reaction time, the glucose concentration value is reported in plasma equivalents and is displayed on meter screen.

4. Intended Use:

TeleRPM Gen2 Blood Glucose Monitoring System is comprised of the TeleRPM Gen2 Blood Glucose Meter and the TeleRPM Blood Glucose Test Strips. TeleRPM Gen2 Blood Glucose Monitoring System is intended to quantitatively measure the glucose concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by persons with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for neonatal use or for the diagnosis of or screening for diabetes. This system is intended for self-testing outside the body (in vitro diagnostic use), and should only be used by a single person and should not be shared.

5. Comparison of Technological Characteristics with Predicate Device:

5.1 Comparison of TeleRPM Gen2 Blood Glucose Monitoring System with the predicate:

Characteristics	Predicate: VivaChek™ Link Plus Blood Glucose Monitoring System (k233058)	Candidate: TeleRPM Gen2 Blood Glucose Monitoring System
Similarities		
Intended Use	It is intended to quantitatively measure the glucose concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by persons with diabetes at home as an aid to monitor the effectiveness of diabetes control.	Same
Operation Principle	Electrochemical biosensor	Same
Detection Method	Amperometric	Same
Strip Chemical Composition	Glucose oxidase	Same
Measurement Result	Plasma Glucose	Same
Sample	Fresh capillary whole blood	Same
Unit of Measure	mg/dL	Same
Measurement Range	20-600 mg/dL	Same
Sample Volume	0.8μL	Same

Test Time	5 seconds	Same
Operating Relative Humidity	10-90% (non-condensing)	Same
Operating Temperature	41–113°F	Same
Hematocrit Range	20-70%	Same
Automatic Shutoff	2 minutes after last action	Same
Power Source	Rechargeable 3.7 Volt DC nominal, lithium polymer battery (5V input charge voltage)	Same
Data Transmission	This meter features automatic transfer of glucose results to the Cloud using 4G wireless mobile communication	Same
Differences		
Battery Capacity	800 mAh	1,300 mAh
Memory	500 records	2,000 records
Dimensions	100.9mm x 61.6mm x 23.7mm	105.2mm x 60.2mm x 17.5mm
Weight	Approximately 85g	Approximately 123g

6. Laboratory (Nonclinical) and Clinical Studies

6.1 Studies/Tests with Performance Data

Study and testing activities included cleaning and disinfection, robustness, precision, linearity, user evaluation, interference evaluation, test strips stability, flex studies. The studies with performance data were provided in the submission to support of the substantial equivalence determination.

TeleRPM Gen2 Blood Glucose Monitoring System contains 4G module, the device complies with software and cybersecurity control guidance requirements based on the test reports and study reports.

6.2 Brief Discussion of Laboratory (Nonclinical) Studies:

Laboratory (nonclinical) studies were performed on the TeleRPM Gen2 Blood Glucose Monitoring System in accordance with the FDA SMBG OTC Guidance, CLSI guidelines and industry standards. Test data and results from laboratory studies showed that these devices performed as intended and met associated guidance documents and industry standards.

6.3 Brief Discussion of Clinical Study including Usability Evaluation:

The TeleRPM Gen2 Blood Glucose Monitoring System has the same intended use, work principle and technological characteristics as VivaChek™ Link Plus Blood Glucose Monitoring System, clinical study (user evaluation) and usability evaluation were conducted with intended users using the TeleRPM Gen2 Blood Glucose Monitoring System. Studies result indicated that inexperienced lay persons were able to obtain blood glucose readings when using the TeleRPM Gen2 Blood Glucose Monitoring System, and the clinical study data showed that the clinical performance met the FDA SMBG OTC Guidance. All participants had the ability of understanding of the labeling, could use of the system and could interpret the testing results and error messages based on the usability evaluation reports. In addition, there was no adverse effect or complication occurred or identified during the clinical study including usability evaluation. Therefore, these studies support the intended use as described in the proposed labeling.

7. Conclusion:

The nonclinical studies and clinical study results demonstrate that the TeleRPM Gen2 Blood Glucose Monitoring System performed as intended and met FDA SMBG OTC Guidance and industry standards. TeleRPM Gen2 Blood Glucose Monitoring System is as safe, as effective and perform as well as the predicate device.

Therefore, the candidate device TeleRPM Gen2 Blood Glucose Monitoring System is substantially equivalent to the predicate device VivaChek Link Plus Blood Glucose Monitoring System (k233058).