December 22, 2023

VivaChek Biotech (Hangzhou) Co., Ltd.
Mark Qian
Quality Director
Level 2, Block 2, 146 East Chaofeng Rd.
Yuhang Economy Development Zone
Hangzhou, Zhejiang 311100
China

Re: K233058
Trade/Device Name: VivaChek™ Link Plus Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: September 20, 2023
Received: September 25, 2023

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.

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.

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,

Yiduo Wu -S

for 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)*
K233058

Device Name
VivaChek™ Link Plus Blood Glucose Monitoring System

Indications for Use *(Describe)*
VivaChek™ Link Plus Blood Glucose Monitoring System is comprised of the VivaChek™ Link Plus Blood Glucose Meter and the VivaChek™ Ino Blood Glucose Test Strips.

VivaChek™ Link Plus 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.

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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Section F: 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Assigned 510(k) number is k233058.

Submitter's Identification:

VivaChek Biotech (Hangzhou) Co., Ltd
Level 2, Block 2, 146 East Chaofeng Rd.,
Yuhang Economy Development Zone,
Hangzhou, 311100, Zhejiang, China.

Date Updated: Dec 19, 2023

Contact Person:

Name: Mark Qian
Position: Quality Director
Email: mark.qian@vivachekbio.com

Proprietary Name of the Device:

VivaChek Link Plus Blood Glucose Monitoring System

Common Name: Glucose Test System

Classification Name:

Class II §862.1345 Glucose Test System
Product Code: NBW

Predicate Device:

VivaChek Ino Smart Blood Glucose Monitoring System
VivaChek Laboratories, Inc.
510(k) Number: k173140

Applicant: VivaChek Biotech (Hangzhou) Co., Ltd
Address: Level 2, Block 2, 146 East Chaofeng Rd.,
Yuhang Economy Development Zone, Hangzhou, 311100, Zhejiang, China
Contact: Mark Qian Email: mark.qian@vivachekbio.com

Section F

Device Name:

Proprietary Name	Meter Model	Test Strips Model	Classification	Product Code	Description	Common Name
VivaChek Link Plus Blood Glucose Monitoring System	VGM90	VGS01	862.1345 Class II	NBW	System, Test, Blood Glucose, Over The Counter	Glucose Test System

Intended Use:

VivaChek Link Plus Blood Glucose Monitoring System is comprised of the VivaChek Link Plus Blood Glucose Meter and the VivaChek Ino Blood Glucose Test Strips. VivaChek Link Plus 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.

Description:

VivaChek Link Plus Blood Glucose Monitoring System is designed to quantitatively measure the glucose concentration in fresh capillary whole blood. 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 in the sample is displayed.

VivaChek Link Plus Blood Glucose Monitoring System contains 4G module, the device complies with US federal guidelines, FCC Part 15 Subpart B, FCC Part 2, FCC Part 24 Subpart E, FCC Part 27 Subpart C, and FCC 47 CFR§ 2.1093 based on the test reports.

Comparison to Predicate Device:

The VivaChek Link Plus Blood Glucose Monitoring System is substantially equivalent to VivaChek Ino Smart Blood Glucose Monitoring System (k173140).

Features	Predicate: VivaChek Ino Smart Blood Glucose Monitoring System (k173140)	Candidate: VivaChek Link Plus 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. It is not intended for neonatal use or for the diagnosis of or screening for diabetes. It 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.	Same
Operation Principle	Electrochemical biosensor	Same
Detection Method	Amperometric	Same
Strip Chemical Composition	Glucose oxidase	Same
Measurement Result	Plasma equivalent	Same
Sample	Fresh capillary whole blood	Same
Memory	500 records	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 Lithium Ion battery	Same
Differences		
Battery Type	Rechargeable, non-serviceable, 250mAh, 3.7 Volt DC nominal, lithium	Rechargeable, 800 mAh, 3.7 Volt DC nominal, lithium polymer battery (5V input

	polymer battery (5V input charge voltage)	charge voltage)
Data Transmission	Bluetooth	4G
Dimensions	83 mm x 52 mm x 18.7 mm	100.9mm x 61.6mm x 23.7mm
Display Size	32mm x 32 mm	42 mm x 41 mm
Weight	Approximately 53g	Approximately 85g

Laboratory and Clinical Testing:

The performance characteristics of the VivaChek Link Plus Blood Glucose Monitoring System were evaluated by performing the following studies:

No.	Test/Validation Item
1	Within-Run Precision Evaluation
2	Intermediate Precision Evaluation
3	Linearity Evaluation Study
4	User Evaluation
5	User Evaluation - Accuracy at Extreme Glucose Values
6	Usability Evaluation
7	Interference Agents Study
8	Accelerated Closed Vial Stability Study
9	Accelerated Open Vial Stability Study
10	System Operating Conditions Evaluation
11	Altitude Effect Evaluation
12	Error Messages Validation
13	Short Sample Detection Study
14	Sample Perturbation Study
15	Intermittent Sampling Study
16	Testing with Used Test Strips
17	Test Strip Early Removal Validation
18	Incorrect Strip Insertion Validation

19	Shipping and Handling Study
20	Oxygen Interference Study
21	Hematocrit Effect Study
22	Meter Environmental Temperature Test
23	Vibration Testing
24	Shock Testing
25	Low Battery Study
26	Recharging Temperature Limit Validation
27	Cleaning and Disinfection Study
28	Meter Robustness Study
29	EMC Testing including the wireless connection testing
30	Electrical Safety Testing
31	FCC Testing
32	Meter Software (Firmware) Validation
33	Cybersecurity Control DFMEA
34	Cybersecurity Management Plan

To confirm the 4G module has not brought any unexpected functional failure or adverse effect, FCC, cybersecurity control DFMEA, Cybersecurity Management Plan and Web App software validation were conducted.

Discussion of Laboratory Studies:

Above laboratory studies were performed on VivaChek Link Plus Blood Glucose Monitoring System in accordance with the applicable guidance or standards, and the test results indicated that the acceptance criteria were met. Therefore, the performances from these laboratory studies were acceptable.

Discussion of Clinical Study:

Clinical study (user evaluation) was conducted with intended users using the VivaChek Link Plus Blood Glucose Monitoring System. Study results indicated that non-professional, inexperienced lay persons were able to obtain blood glucose readings when using the VivaChek Link Plus Blood Glucose Monitoring System. In addition, the participated lay persons were questioned and responded as satisfied with the ease of operation by following the User Manual and the overall performance of the VivaChek Link Plus Blood Glucose Monitoring System.

Conclusion:

The laboratory studies and user evaluation study results demonstrate that the VivaChek Link Plus Blood Glucose Monitoring System is safe, effective and easy-to-use. It also demonstrates that the VivaChek Link Plus Blood Glucose Monitoring System meets FDA Guidance SMBG for OTC Use.

Based on the same intended use and work principle, and the same technological characteristics listed in the section Comparison to Predicate Device - Similarities, meanwhile the different technological characteristics listed in the section Comparison to Predicate Device do not raise safety and effectiveness questions according to the completed performance testing and validation reports, therefore the candidate device VivaChek Link Plus Blood Glucose Monitoring System is substantially equivalent to the predicate device VivaChek Ino Smart Blood Glucose Monitoring System (k173140).