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

August 16, 2024

Re: K222126
Trade/Device Name: VivaChek™ Fad Blood Glucose Monitoring System,
VivaChek™ Fad Smart Blood Glucose Monitoring System,
VivaChek™ Fad Sync Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: July 21, 2023
Received: July 21, 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.

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.

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)*
k222126

Device Name
VivaChek™ Fad Blood Glucose Monitoring System

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

VivaChek™ Fad 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*
k222126

Device Name
VivaChek™ Fad Smart Blood Glucose Monitoring System

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

VivaChek™ Fad Smart 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)

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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)*
k222126

Device Name
VivaChek™ Fad Sync Blood Glucose Monitoring System

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

VivaChek™ Fad Sync 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)

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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 k222126.

1. Submitter's Information

1.1 Submitter's Name, Address and Telephone Number

Name: VivaChek Biotech (Hangzhou) Co., Ltd

Address: Level 2, Block 2, 146 East Chaofeng Rd.,
Yuhang Economy Development Zone,
Hangzhou, 311100, Zhejiang, China.

Telephone: +86 571 8918 9521

1.2 Contact Person

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

1.3 Date Updated for Summary

Aug 12, 2024

2. Devices Name

2.1 Proprietary Name:

VivaChek™ Fad Blood Glucose Monitoring System
VivaChek™ Fad Smart Blood Glucose Monitoring System
VivaChek™ Fad Sync 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: TD-4183 Blood Glucose Monitoring System.

510(k) Number: K190579.

Applicant: TaiDoc Technology Corporation.

No reference device was used in this submission.

3. Devices Description

VivaChek™ Fad Blood Glucose Monitoring System consists of VivaChek™ Fad Blood Glucose Meter and the VivaChek™ Fad Blood Glucose Test Strips. The glucose meter and test strips are packaged separately.

VivaChek™ Fad Smart Blood Glucose Monitoring System consists of VivaChek™ Fad Smart Blood Glucose Meter and the VivaChek™ Fad Blood Glucose Test Strips. The glucose meter and test strips are packaged separately.

VivaChek™ Fad Sync Blood Glucose Monitoring System consists of VivaChek™ Fad Sync Blood Glucose Meter and the VivaChek™ Fad Blood Glucose Test Strips. The glucose meter and test strips are packaged separately.

VivaChek Fad Control Solution, VivaChek Lancing Device, VivaChek Lancets are required for use but not included in meter box or test strips box and should be purchased separately. The VivaChek Fad 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. VivaChek Lancing Device and VivaChek Lancets are used for puncturing fingertip and then user can perform glucose test with blood sample.

VivaChek™ Fad Blood Glucose Monitoring System, VivaChek™ Fad Smart Blood Glucose Monitoring System and VivaChek™ Fad Sync Blood Glucose Monitoring System are 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 dehydrogenase 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.

4. Intended Use:

VivaChek™ Fad Blood Glucose Monitoring System is comprised of the VivaChek™ Fad Blood Glucose Meter and the VivaChek™ Fad Blood Glucose Test Strips. VivaChek™ Fad 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.

VivaChek™ Fad Smart Blood Glucose Monitoring System is comprised of the VivaChek™ Fad Smart Blood Glucose Meter and the VivaChek™ Fad Blood Glucose Test Strips. VivaChek™ Fad Smart 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.

VivaChek™ Fad Sync Blood Glucose Monitoring System is comprised of the VivaChek™ Fad Sync Blood Glucose Meter and the VivaChek™ Fad Blood Glucose Test Strips. VivaChek™ Fad Sync 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 VivaChek™ Fad Blood Glucose Monitoring System with the predicate.

Characteristics	Predicate: TD-4183 Blood Glucose Monitoring System (K190579)	Candidate: VivaChek™ Fad Blood Glucose Monitoring System
Similarities		
Intended Use	It is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the fingertip. This 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 the diabetes control program. It is intended to be used by single person and should not be shared. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.	Same
Work (Operation) Principle	Electrochemical biosensor technology	Same
Detection Method	Amperometry	Same
Strip Chemical Composition	Glucose Dehydrogenase -FAD	Same
Test Measured	Glucose in fingertip capillary whole blood	Same
Sample Type	Fresh capillary whole blood	Same
Unit of Measurement	mg/dL	Same
Operating Relative Humidity	10-90%	Same
Differences		
Measurement Range	20 to 650 mg/dL	20 to 600 mg/dL
Test Time	6 seconds	5 seconds
Sample Size	0.5μL	0.8μL
Hematocrit Range	20-65%	20-70%
Strips Storage	35.6-86°F, 10-85% RH	36-86°F, 10-90% RH
Power Source	1 x 1.5V AAA battery	One (1) CR 2032 3.0V coin cell battery

5.2 Comparison of VivaChek™ Fad Smart Blood Glucose Monitoring System and VivaChek™ Fad Sync Blood Glucose Monitoring System with the predicate.

Characteristics	Predicate: TD-4183 Blood Glucose Monitoring System (K190579)	Candidate: VivaChek™ Fad Smart Blood Glucose Monitoring System	Candidate: VivaChek™ Fad Sync Blood Glucose Monitoring System
Similarities			
Intended Use	It is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the fingertip. This 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 the diabetes control program. It is intended to be used by single person and should not be shared. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.	Same	Same
Work (Operation) Principle	Electrochemical biosensor technology	Same	Same
Detection Method	Amperometry	Same	Same
Strip Chemical Composition	Glucose Dehydrogenase -FAD	Same	Same
Test Measured	Glucose in fingertip capillary blood	Same	Same
Sample Type	Fresh capillary whole blood	Same	Same
Unit of Measurement	mg/dL	Same	Same
Operating Relative Humidity	10-90%	Same	Same
Differences			
Measurement Range	20 to 650 mg/dL	20 to 600 mg/dL	20 to 600 mg/dL
Test Time	6 seconds	5 seconds	5 seconds
Sample Size	0.5μL	0.8μL	0.8μL
Hematocrit Range	20-65%	20-70%	20-70%
Strips Storage	35.6-86°F, 10-85% RH	36-86°F, 10-90% RH	36-86°F, 10-90% RH
Power Source	1 x 1.5V AAA battery	Rechargeable, 250mAh, 3.7 volts, lithium polymer battery	Rechargeable, 250mAh, 3.7 volts, lithium polymer battery

6. Laboratory (Nonclinical) and Clinical Studies

6.1 Studies/Tests with Performance Data

Studies and testing activities included cleaning and disinfection, robustness, precision, linearity, user evaluation, usability evaluation, interference, flex studies including electrical safety test and electromagnetic compatibility test, software validation. The following laboratory and clinical studies with performance data were provided in the submission to support of the substantial equivalence determination.

No.	Study/Test Item
1	Cleaning and Disinfection Study
2	Meter Robustness Study
3	Within-Run Precision Evaluation
4	Intermediate Precision Evaluation
5	Linearity Evaluation Study
6	User Evaluations
7	Usability Evaluations
8	Interference Agents Study
9	Hematocrit Effect Study
10	Accelerated Closed Vial Stability Studies
11	Accelerated Open Vial Stability Studies
12	Real Time Closed Vial Stability Studies
13	Real Time Open Vial Stability Studies
14	Sample Perturbation Study
15	Short Sample Detection Study
16	Low Battery Study
17	Altitude Effect Evaluation
18	Operating Conditions Evaluation
19	Intermittent Sampling Study
20	Vibration Test, Shock Test
21	Meter Environmental Temperature Test

22	Error Message Test
23	Testing with Used Test Strips
24	Test Strip Early Removal Validation
25	Incorrect Strip Insertion Validation
26	Recharging Temperature Limit Validation
27	FCC Tests
28	Electrical Safety Test
29	Electromagnetic Compatibility Test
30	Meter Software Documentation etc.

6.2 Brief Discussion of Laboratory (Nonclinical) Studies:

Laboratory (nonclinical) studies were performed on the VivaChek™ Fad Blood Glucose Monitoring System, VivaChek™ Fad Smart Blood Glucose Monitoring System and VivaChek™ Fad Sync 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 Studies including Usability Evaluations:

Since the VivaChek™ Fad Sync Blood Glucose Monitoring System has the same intended use, work principle and technological characteristics as VivaChek™ Fad Smart Blood Glucose Monitoring System, clinical studies (user evaluations) were conducted with intended users using the VivaChek™ Fad Blood Glucose Monitoring System and VivaChek™ Fad Smart Blood Glucose Monitoring System. Usability evaluation was performed on VivaChek™ Fad Blood Glucose Monitoring System, VivaChek™ Fad Smart Blood Glucose Monitoring System, and VivaChek™ Fad Sync Blood Glucose Monitoring System respectively.

Studies result indicated that non-professional, inexperienced lay persons were able to obtain blood glucose readings when using the VivaChek™ Fad Blood Glucose Monitoring System and VivaChek™ Fad Smart Blood Glucose Monitoring System. The clinical studies data showed that the clinical performance met the FDA SMBG OTC Guidance. And all participants had the ability of understanding of the labeling, could use of systems 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 studies including usability evaluations. Therefore, these studies support the intended use as described in the proposed labeling.

7. Conclusion:

The nonclinical studies and clinical studies results demonstrate that the VivaChek™ Fad Blood Glucose Monitoring System and VivaChek™ Fad Smart Blood Glucose Monitoring System performed as intended and met FDA SMBG OTC Guidance and industry standards. The different characteristics listed in Section 5 of this summary do not raise safety and effectiveness questions according to the completed and accepted nonclinical and clinical studies. VivaChek™ Fad Blood Glucose Monitoring System and VivaChek™ Fad Smart Blood Glucose Monitoring System are as safe, as effective and perform better than the predicate device.

As described in the Section 6.3 above, VivaChek™ Fad Sync Blood Glucose Monitoring System has the same intended use, work principle and technological characteristics as VivaChek™ Fad Smart Blood Glucose Monitoring System, and based on the laboratory studies results, the user evaluation result from VivaChek™ Fad Smart Blood Glucose Monitoring System, and usability evaluation for VivaChek™ Fad Sync Blood Glucose Monitoring System. VivaChek™ Fad Sync Blood Glucose Monitoring System is also as safe, as effective and performs better than the predicate device.

Therefore, VivaChek™ Fad Blood Glucose Monitoring System, VivaChek™ Fad Smart Blood Glucose Monitoring System, and VivaChek™ Fad Sync Blood Glucose Monitoring System are substantially equivalent to the predicate device.