June 5, 2020

Vivachek Biotech (Hangzhou) Co., Ltd
Mark Qian
Quality Director
1/2/3 F, Building 1, 16 East Zhenxing Rd., Yuhang
Hangzhou, 311100 China

Re: K192957
Trade/Device Name: VivaChek™ Blood Glucose and β-Ketone Monitoring System
Regulation Number: 21 CFR 862.1435
Regulation Name: Ketones (nonquantitative) test system
Regulatory Class: Class I, meets the limitation of exemption 21 CFR 862.9(c)(5)
Product Code: JIN
Dated: May 11, 2020
Received: May 14, 2020

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 (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.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k192957

Device Name
VivaChek™ Blood Glucose and β-Ketone Monitoring System

Indications for Use *(Describe)*

VivaChek™ Blood Glucose and β-Ketone Monitoring System is comprised of the VivaChek™ Blood Glucose and β-Ketone Meter (VGM200), the VivaChek™ Ino Blood Glucose Test Strips (VGS01) and the VivaChek™ Blood β-Ketone Test Strips (VKS01).

The VivaChek™ Blood Glucose and β-Ketone Monitoring System is intended to quantitatively measure the glucose concentration and/or β-ketone (beta-hydroxybutyrate) 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.

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Section G. 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 k192957.

Submitter's Identification:

VivaChek Biotech (Hangzhou) Co., Ltd

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Tel: +86-571-8918-9521

Date Updated: Jun 05, 2020

Contact Person:

Mark Qian
Quality Director

VivaChek Biotech (Hangzhou) Co., Ltd

1/2/3 F, Building 1, 16 East Zhenxing Rd., Yuhang Economy Development Zone,
Yuhang, Hangzhou, 311100, Zhejiang, China

Proprietary Name:

VivaChek™ Blood Glucose and β-Ketone Monitoring System

Common Name:

Blood Glucose and β-Ketone Test System

Classification Name:

Class II 21 CFR §862.1345 Glucose Test System

Product code: NBW

Class I, 21 CFR §862.1435 Ketones (nonquantitative) test system, meets limitations of exemptions 21 CFR 862.9(c)(5).

Product code: JIN

Predicate Device Name:

KetoSens Blood β-Ketone Monitoring System

Predicate K Number:

K170463

Description:

VivaChek™ Blood Glucose and β-Ketone Monitoring System (Model: VGM200) is designed to quantitatively measure the glucose and/or β-ketone concentration respectively in fresh capillary whole blood samples drawn from the fingertips.

The test principle of the β-ketone is based on the amperometric detection of β-hydroxybutyrate (also known as 3-hydroxybutyrate) in whole blood. β-hydroxybutyrate is converted by the enzyme β-hydroxybutyrate dehydrogenase to acetoacetate. The magnitude of electrical current resulting from this enzymatic reaction is proportional to the amount of β-hydroxybutyrate present in the sample.

VivaChek™ Blood Glucose and β-Ketone Monitoring System (Model: VGM200) contains Bluetooth Low Energy (BLE), it complies with US federal guidelines, Part 15 of the FCC Rules for devices with RF capability. Refer to the relative FCC Test Reports in this submission.

Intended Use:

VivaChek™ Blood Glucose and β-Ketone Monitoring System is comprised of the VivaChek™ Blood Glucose and β-Ketone Meter (VGM200), the VivaChek™ Ino Blood Glucose Test Strips (VGS01) and the VivaChek™ Blood β-Ketone Test Strips (VKS01).

The VivaChek™ Blood Glucose and β-Ketone Monitoring System is intended to quantitatively measure the glucose concentration and/or β-ketone (beta-hydroxybutyrate) 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.

Technological Characteristics:

Specification of VivaChek™ Blood Glucose and β-Ketone Monitoring System (Model: VGM200):

Feature	**Specification**
Measurement Range	Blood glucose: 20 - 600mg/dL; Blood β-ketone: 0.1 - 8.0 mmol/L
Test Measured	Blood Glucose and/or β-Ketone in fingertip capillary whole blood
Operating Principle	Amperometric
Sample	Fresh capillary whole blood
Sample Volume	Blood glucose: 0.8 µL; Blood β-ketone: 0.8 µL
Test Time	Blood glucose: 5 seconds; Blood β-ketone: 10 seconds
Power Source	Two AAA LR03 1.5V batteries
Units of Measure	Blood glucose: Milligrams per deciliter (mg/dL) ; Blood β-ketone: Millimoles per liter (mmol/L)
Memory	Up to 1000 records
Automatic Shutoff	2 minutes after last action
Operating Temperature	45.5-113°F
Operating RH	10-90%
Hematocrit Range	20-65%
Battery Life	12 months or approximately 1,000 tests
Bluetooth	Bluetooth Low Energy (BLE)

Comparison to Predicate Device on Technological Characteristics:

VivaChek Blood Glucose and β-Ketone Monitoring System (Model: VGM200) is substantially equivalent to:

	Predicate Device	**Candidate Device**
Features	KetoSens Blood β-Ketone Monitoring System (K170463)	VivaChek™ Blood Glucose and β-Ketone Monitoring System (Model: VGM200)
Similarities		
Intended Use	For the quantitative measurement of β-Ketone in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control program. The system is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. This system is intended to be used by a single person and should not be shared.	Same
Use Type	Single patient use	Same
Specimen	Capillary whole blood from the fingertips	Same
Measurement Method	Amperometric	Same
Measurement Range	0.1 - 8.0 mmol/L	Same
Strip Active Reagent	β-hydroxybutyrate dehydrogenase	Same
Operating Relative Humidity	10–90%	Same
Test Strip Calibration Coding	Auto-coding	Same
Differences		
Operating Temperature	50-100°F	45.5-113°F
Sample Volume	0.5 μL	0.8 μL
Hematocrit Range	20-55%	20-65%

Laboratory Testing:

The performance characteristics of the VivaChek™ Blood Glucose and β-Ketone Monitoring System were evaluated by performing the following non-clinical studies:

No.	Study	Conclusion
1	Linearity Study	Pass
2	User Evaluation	Pass
3	Accelerated Closed Vial Test Strip Stability Study	Pass
4	Accelerated Closed Control Stability Study	Pass
5	Accelerated Open Vial Test Strip Stability Study	Pass
6	Real Time Open Vial Test Strip Stability Study	Pass
7	Hematocrit Effect Study	Pass
8	Sample Volume Study	Pass
9	Intermediate Precision Study	Pass
10	Within-Run Precision Study	Pass
11	Altitude Effect Evaluation	Pass
12	Operating Conditions Evaluation	Pass
13	Shipping Study for Ketone Test Strip	Pass
14	Shipping Study for Ketone Control	Pass
15	Interference Agents Study	Pass
16	Error Codes Test	Pass
17	Meter Environmental Temperature Test	Pass
18	Testing with Used Test Strips	Pass
19	Meter Software Documentation	Pass
20	Meter Robustness Study	Pass

Brief Discussion of Non-Clinical Studies:

Above non-clinical (laboratory) studies were performed on the VivaChek™ Blood Glucose and β-Ketone Monitoring System in accordance with the corresponding study protocols, and the test results indicated that the acceptance criteria were met. Therefore the ketone performances from these non-clinical (laboratory) studies were acceptable.

Brief Discussion of Clinical Study:

User evaluation study was conducted in accordance with the User Evaluation Study Protocol on VivaChek™ Blood Glucose and β-Ketone Monitoring System. Study results indicated that non-professional, inexperienced lay persons were able to obtain β-ketone readings when using the VivaChek™ Blood Glucose and β-Ketone Monitoring System. In addition, the participated lay persons were questioned and responded as satisfied with the ease of operation by following User Manual and the overall ketone measurement performance of the VivaChek™ Blood Glucose and β-Ketone Monitoring System.

Conclusion:

The non-clinical (laboratory) studies and clinical (user evaluation) study results have demonstrated that the VivaChek™ Blood Glucose and β-Ketone Monitoring System is safe, effective and easy-to-use, besides it demonstrated that the VivaChek™ Blood Glucose and β-Ketone Monitoring System meets applicable CLSI guidelines, and also based on the similarities described in the table of Comparison to Predicate Device on Technological Characteristics in this 510(k) summary. VivaChek™ Blood Glucose and β-Ketone Monitoring System is substantially equivalent to the KetoSens Blood β-Ketone Monitoring System (K170463).