DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 21, 2017

VIVACHEK LABORATORIES, INC.
JULIE ZHOU
MANAGER OF REGULATORY AFFAIR DEPARTMENT
913 N MARKET STREET, SUITE 200
WILMINGTON DE 19081

Re: K160179
Trade/Device Name: VivaChek Ino Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: April 7, 2017
Received: April 10, 2017

Dear Julie Zhou:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160179

Device Name
VivaChek™ Ino Blood Glucose Monitoring System

Indications for Use *(Describe)*
VivaChek™ Ino Blood Glucose Monitoring System is comprised of the VivaChek™ Ino Blood Glucose Meter and the VivaChek™ Ino Blood Glucose Test Strips. The VivaChek™ Ino Blood Glucose Monitoring System (Meter Model: VGM01) is designed to quantitatively measure the glucose concentration in fresh capillary whole blood. It allows diabetics to take blood samples from the fingertip, forearm, or palm. It is used at home as a way to monitor the effectiveness of diabetes control programs. Alternate testing sites (forearm and palm) should be used only during steady-state times (when blood glucose level is not changing rapidly). This system is intended to be used by a single patient and should not be shared.

The VivaChek™ Ino Blood Glucose Monitoring System is not used for the diagnosis of or screening of diabetes or for neonatal use.

The VivaChek™ Ino Blood Glucose Control Solution is for use with the VivaChek™ Ino Blood Glucose Meter and Strips as a quality control check to verify that the meter and test strip are working together properly, and that the test is performing correctly

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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Sponsor: VivaChek Labortatories, Inc.
Address: 913 N Market Street, Suite 200, Wilmington, DE, 19801, USA
Contact: Ms. Monica.Huang
Email: monica.huang@vivachek.com. Tel / Fax: +1-302-339-8107

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 __K160179__ _____.

Submitter's Identification:

VivaChek Laboratories, Inc.
913 N Market Street,
Wilmington, DE, 19801, USA

Tel/Fax.: 302-339-8107

Date Prepared: Dec, 2015

Contact Person:

Monica Huang
Regulatory Affairs Manager

Proprietary Name of the Device:

VivaChek™ Ino Blood Glucose Monitoring System

Common Name:

Glucose Test System

Classification Name:

Class II §862.1345 Glucose Test System

Predicate Device:

One Touch Ultra Blood Glucose Monitoring System
Lifescan, Inc., located at 1000 Gibraltar Dr., Milpitas, CA 95035, USA.
K002134

LifeScan One Touch Ultra Control Solution
Bionostics, Inc., located at 7Jackson Road, Devens, MA01432, USA.
510(k) Number: K022769

Sponsor: VivaChek Labortatories, Inc.
Address: 913 N Market Street, Suite 200, Wilmington, DE, 19801, USA
Contact: Ms. Monica.Huang
Email: monica.huang@vivachek.com. Tel / Fax: +1-302-339-8107

Device Name: VivaChek™ Ino Blood Glucose Monitoring System

Proprietary Name	Classification	Product Code	Description	Common Name
VivaChek™ Ino Blood Glucose Monitoring System	862.1345 Class II	75 NBW	System, Test, Blood Glucose, Over The Counter	Glucose Test System
VivaChek™ Ino Blood Glucose Meter and Blood Glucose Test Strips	862.1345 Class II	75 CGA	Glucose Monitor	Glucose Meter & Test Strips
VivaChek™ Ino Glucose Control Solution	862.1660 Class I	75 JJX	Single Analyte Control	Control Solution

Description:

The VivaChek™ Ino Blood Glucose Monitoring System (Meter Model: VGM01) 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 enzyme 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. The meter is calibrated to display plasma-like concentration results.

All 3 levels control solution consists of glucose in water with buffers and a preservative, and a dye. The device is formulated to provide low, normal and high glucose values representative of low, normal and high blood glucose values in subjects. The active ingredient, glucose, is the same analyte measured in blood specimens by the relevant blood glucose test systems. The proprietary characteristics of the solution have been modified to mimic the measurement of blood specimens with this non-biological, non-toxic, aqueous solution. The product does not contain red blood cells, and so, cannot be used to assess hematocrit effects on glucose measurement. The solution has a red color to enhance its visibility.

Intended Use:

VivaChek™ Ino Blood Glucose Monitoring System is comprised of the VivaChek™ Ino Blood Glucose Meter and the VivaChek™ Ino Blood Glucose Test Strips. The VivaChek™ Ino Blood Glucose Monitoring System (Meter Model: VGM01) is designed to quantitatively measure the glucose concentration in fresh capillary whole blood. It allows diabetics to take blood samples from the fingertip, forearm, or palm. It is used at home as a way to monitor the effectiveness of diabetes control programs. Alternate testing sites (forearm and palm) should be used only during steady-state times (when blood glucose level is not changing rapidly). This system is intended to be used by a single patient and should not be shared.

The VivaChek™ Ino Blood Glucose Monitoring System is not used for the diagnosis of or screening of diabetes or for neonatal use.

The VivaChek™ Ino Blood Glucose Control Solution is for use with the VivaChek™ Ino Blood Glucose Meter and Strips as a quality control check to verify that the meter and test strip are working together properly, and that the test is performing correctly.

Technological Characteristics:

Specification of Blood Glucose Meter:

Feature	Specification
Measurement range	20 to 600 mg/dL
Result calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Sample volume:	0.8 µL
Test time	5 seconds
Power source	Two (2) CR 2032 3.0 V coin cell batteries
Battery life	12 months or approximately 1,000 tests
Glucose units of measure	The meter is pre-set to milligrams per deciliter (mg/dL)
Memory	Up to 900 records with date and time
Automatic shutoff	2 minutes after last action
Dimensions	82.5 mm × 52 mm × 18.2 mm
Display size	31mm × 37 mm
Weight	Approximately 47g (with battery installed)
Operating temperature	41-113°F
Operating relative humidity	10-90% (non-condensing)
Hematocrit range	20-70%
Data Port	mini USB

Comparison to Predicate Devices:

The VivaChek™ Ino Blood Glucose Monitoring System is substantially equivalent to One Touch Ultra Blood Glucose Monitoring System, K002134.

Features	VivaChek™ Ino Blood Glucose Monitoring System	One Touch Ultra Blood Glucose Monitoring System (K002134)
Similarities		
Assay Method	Glucose oxidase biosensor	Same
Strip Chemical Composition	Glucose oxidase, Mediator	Same
Result Calibration	Plasma-equivalent	Same
Test Time	5 seconds	Same
Sample Type	Fresh capillary whole blood	Same
Glucose Units of Measure	mg/dL	Same
Operating Relative Humidity	10–90%	Same

Data Port	mini USB	One Serial data port
Automatic Shutoff	2 minutes after last action	Same
Differences		
Measurement Range	20 to 600 mg/dL	20 to 600 mg/dL
Minimum Sample Size	0.8 µL	1.0 µL
Hematocrit Range	20–70%	30–55%
Operating Temperature	5–45°C (41–113°F)	6–44°C (43–111°F)
Alternative Sample Site for Capillary	Palm and forearm in addition to fingertip	Fingertip and forearm
Meter Memory	Up to 900 records with time and date	150 blood glucose and control solution tests
Battery Life	12 months or approximately 1,000 tests	1,000 tests
Power Source	Two (2) CR 2032 3.0V coin cell batteries	One (1) CR 2032 3.0V coin cell battery
Meter Size	82.5 mm × 52 mm × 18.2 mm	3.12” x 2.25” x 0.85”
Meter Weight	Approximately 47g (with battery installed)	1.5 ounces with battery (Approximately 42 g)

Comparison to Predicate Control solution

Similarities and Differences		
Item	Proposed Device VivaChek™ Ino Control Solution	Predicate Device(K022769)
Indications for use	Same	LifeScan One Touch Ultra control solution is intended for use to verify verify the performance of blood glucose monitoring system. The control solution is intended for use by healthcare professionals and people with diabetes mellitus at home. For In Vitro Diagnostic Use
Analyte	Same	D-glucose
Matrix	Buffered aqueous solution of D-glucose, preservatives and other non-reactive ingredients.	Buffered aqueous solution of D-glucose, a viscosity modifier, preservatives and other non-reactive ingredients.
Number of levels	3	1
Target Value	Approximately 50mg/dL for level1, approximately 120mg/dL for level2 and approximately 350mg/dL for level3,	Approximately 115mg/dL
Blood Glucose Meters	VivaChek™ Ino	LifeScan OneTouch Ultra

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Guidance documents included the “FDA Guidance for Industry In Vitro Diagnostic Glucose Test System” and “FDA Guidance for Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems” as well as “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”

Compliance to applicable voluntary standards includes EN ISO 15197:2013 "*In vitro* diagnostic test systems – Requirements for in vitro whole blood glucose monitoring systems intended for use by patients for self testing in management of diabetes mellitus."

Laboratory Testing:

The performance characteristics of the VivaChek™ Ino Blood Glucose Monitoring System were evaluated by performing the following studies: repeatability precision, intermediate precision, linearity, interfering agents, hematocrit effect, temperature effect evaluation – blood & control solution, low battery effect, altitude effect, sample volume, humidity effect, simulated shipping study – test strip & control solution, strip accelerated stability, strip real time stability, strip real time use life, control value assignment, control solution accelerated stability, control solution real time stability, control solution real time use life, meter testing, software validation testing, electromagnetic compatibility and electrical safety testing as part of meter and strip validation testing.

Discussion of Clinical Tests Performed:

Clinical studies were conducted with lay persons and trained laboratory technicians using the VivaChek™ Ino Blood Glucose Monitoring System. The study data were presented evaluating the system accuracy of the VivaChek™ Ino Blood Glucose Monitoring System compared to the YSI Model 2300 STAT PLUS (K913806) per the VivaChek Clinical Study Protocol for the Blood Glucose Monitoring System. Study results indicate that non-professional, inexperienced lay persons were able to obtain comparable blood glucose readings when using the VivaChek™ Ino Blood Glucose Monitoring System. In addition, the participating lay persons were questioned and responded as satisfied with the ease of operation by following the Instructions for Use in the User's Manual and the overall performance of the VivaChek™ Ino Blood Glucose Monitoring System.

Conclusion:

The laboratory testing and clinical study results demonstrate that the VivaChek™ Ino Blood Glucose Monitoring System is safe, effective and easy-to-use. It also demonstrates that the VivaChek™ Ino Blood Glucose Monitoring System meets the accuracy requirements per EN ISO 15197 and as such is substantially equivalent to the One Touch Ultra Blood Glucose Monitoring System, currently sold on the U.S. market (K002134).