December 19, 2018

VivaChek Laboratories, Inc.
Julie Zhou
Manager of Regulatory Affair Department
913 N Market Street, Suite 200
Wilmington, DE 19081

Re: K173140
Trade/Device Name: VivaChek Ino Smart Blood Glucose Monitoring System
VivaChek Ino Sync Blood Glucose Monitoring System
VivaChek Ino Sound Blood Glucose Monitoring System
VivaChek Ino Plus Blood Glucose Monitoring System
VivaChek Ino Sound Simple Blood Glucose Monitoring System
VivaChek Ino Sound Bright Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: November 8, 2018
Received: November 16, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173140

Device Name
VivaChek™ Ino Smart Blood Glucose Monitoring System

Indications for Use *(Describe)*
VivaChek™ Ino Smart Blood Glucose Monitoring System is comprised of the VivaChek™ Ino Smart Blood Glucose Meter (VGM04) and the VivaChek™ Ino Blood Glucose Test Strips (VGS01). The VivaChek™ Ino 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173140

Device Name
VivaChek™ Ino Sync Blood Glucose Monitoring System

Indications for Use *(Describe)*
VivaChek™ Ino Sync Blood Glucose Monitoring System is comprised of the VivaChek™ Ino Sync Blood Glucose Meter (VGM05) and the VivaChek™ Ino Blood Glucose Test Strips (VGS01). The VivaChek™ Ino 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)*

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Indications for Use

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Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173140

Device Name
VivaChek™ Ino Sound Blood Glucose Monitoring System

Indications for Use *(Describe)*
VivaChek™ Ino Sound Blood Glucose Monitoring System is comprised of the VivaChek™ Ino Sound Blood Glucose Meter (VGM09) and the VivaChek™ Ino Blood Glucose Test Strips (VGS01). The VivaChek™ Ino Sound 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)*

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Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K173140

Device Name
VivaChek™ Ino Plus Blood Glucose Monitoring System

Indications for Use *(Describe)*
VivaChek™ Ino Plus Blood Glucose Monitoring System is comprised of the VivaChek™ Ino Plus Blood Glucose Meter (VGM22) and the VivaChek™ Ino Blood Glucose Test Strips (VGS01). The VivaChek™ Ino 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)

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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173140

Device Name
VivaChek™ Ino Sound Simple Blood Glucose Monitoring System

Indications for Use *(Describe)*
VivaChek™ Ino Sound Simple Blood Glucose Monitoring System is comprised of the VivaChek™ Ino Sound Simple Blood Glucose Meter (VGM26) and the VivaChek™ Ino Blood Glucose Test Strips (VGS01). The VivaChek™ Ino Sound Simple 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)*

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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173140

Device Name
VivaChek™ Ino Sound Bright Blood Glucose Monitoring System

Indications for Use *(Describe)*
VivaChek™ Ino Sound Bright Blood Glucose Monitoring System is comprised of the VivaChek™ Ino Sound Bright Blood Glucose Meter (VGM27) and the VivaChek™ Ino Blood Glucose Test Strips (VGS01). The VivaChek™ Ino Sound Bright 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 being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Assigned 510(k) number is __K173140_____.

Submitter's Identification:

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

Tel/Fax.: 302-339-8107

Date Updated: Dec 18, 2018

Contact Person:

Julie Zhou
Regulatory Affairs Manager
VivaChek Laboratories, Inc.
913 N Market Street,
Wilmington, DE, 19801, USA

Proprietary Name of the Device:

VivaChek™ Ino Smart Blood Glucose Monitoring System
VivaChek™ Ino Sync Blood Glucose Monitoring System
VivaChek™ Ino Sound Blood Glucose Monitoring System
VivaChek™ Ino Plus Blood Glucose Monitoring System
VivaChek™ Ino Sound Simple Blood Glucose Monitoring System
VivaChek™ Ino Sound Bright 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 Blood Glucose Monitoring System
VivaChek Laboratories, Inc.
913 N Market Street, Wilmington, DE, 19801, USA
510(k) Number: K160179

Device Name:

Proprietary Name	Model No.	Classification	Product Code	Description	Common Name
VivaChek™ Ino Smart Blood Glucose Monitoring System	VGM04	862.1345 Class II	NBW	System, Test, Blood Glucose, Over The Counter	Glucose Test System
VivaChek™ Ino Sync Blood Glucose Monitoring System	VGM05	862.1345 Class II	NBW	System, Test, Blood Glucose, Over The Counter	Glucose Test System
VivaChek™ Ino Sound Blood Glucose Monitoring System	VGM09	862.1345 Class II	NBW	System, Test, Blood Glucose, Over The Counter	Glucose Test System
VivaChek™ Ino Plus Blood Glucose Monitoring System	VGM22	862.1345 Class II	NBW	System, Test, Blood Glucose, Over The Counter	Glucose Test System
VivaChek™ Ino Sound Simple Blood Glucose Monitoring System	VGM26	862.1345 Class II	NBW	System, Test, Blood Glucose, Over The Counter	Glucose Test System
VivaChek™ Ino Sound Bright Blood Glucose Monitoring System	VGM27	862.1345 Class II	NBW	System, Test, Blood Glucose, Over The Counter	Glucose Test System

Description:

VivaChek™ Ino Smart Blood Glucose Monitoring System (Model: VGM04) 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.

VivaChek™ Ino Sync Blood Glucose Monitoring System (Model: VGM05), VivaChek™ Ino Sound Blood Glucose Monitoring System (Model:VGM09), VivaChek™ Ino Plus Blood Glucose Monitoring System (Model:VGM22), VivaChek™ Ino Sound Simple Blood Glucose Monitoring System (Model: VGM26), VivaChek™ Ino Sound Bright Blood Glucose Monitoring System (Model: VGM27) are 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.

VivaChek™ Ino Smart Blood Glucose Monitoring System (Model: VGM04), VivaChek™ Ino Sync Blood Glucose Monitoring System (Model: VGM05), VivaChek™ Ino Sound Blood Glucose Monitoring System (Model: VGM09) and VivaChek™ Ino Plus Blood Glucose Monitoring System (Model:VGM22) contain Bluetooth, the devices comply with US federal guidelines, Part 15 of the FCC Rules for devices with RF capability. Please refer to the FCC PART 15.247 BLE Test Reports #1803WSU007-U1 for VGM09 and VGM22 systems, and #1803WSU007-U2 for VGM04 and VGM05 systems.

VivaChek™ Ino Sound Blood Glucose Monitoring System (Model: VGM09), VivaChek™ Ino Sound Simple Blood Glucose Monitoring System（Model: VGM26）and VivaChek™ Ino Sound Bright Blood Glucose Monitoring System (Model: VGM27) contain talking functionality, refer to Talking Feature Validation Protocols and Reports, and Meter Robustness Study Protocol and Report.

Intended Use:

VivaChek™ Ino Smart Blood Glucose Monitoring System is comprised of the VivaChek™ Ino Smart Blood Glucose Meter (VGM04) and the VivaChek™ Ino Blood Glucose Test Strips (VGS01). The VivaChek™ Ino 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™ Ino Sync Blood Glucose Monitoring System is comprised of the VivaChek™ Ino Sync Blood Glucose Meter (VGM05) and the VivaChek™ Ino Blood Glucose Test Strips (VGS01). The VivaChek™ Ino 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.

VivaChek™ Ino Sound Blood Glucose Monitoring System is comprised of the VivaChek™ Ino Sound Blood Glucose Meter (VGM09) and the VivaChek™ Ino Blood Glucose Test Strips (VGS01). The VivaChek™ Ino Sound 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™ Ino Plus Blood Glucose Monitoring System is comprised of the VivaChek™ Ino Plus Blood Glucose Meter (VGM22) and the VivaChek™ Ino Blood Glucose Test Strips (VGS01). The VivaChek™ Ino 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.

VivaChek™ Ino Sound Simple Blood Glucose Monitoring System is comprised of the VivaChek™ Ino Sound Simple Blood Glucose Meter (VGM26) and the VivaChek™ Ino Blood Glucose Test Strips (VGS01). The VivaChek™ Ino Sound Simple 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™ Ino Sound Bright Blood Glucose Monitoring System is comprised of the VivaChek™ Ino Sound Bright Blood Glucose Meter (VGM27) and the VivaChek™ Ino Blood Glucose Test Strips (VGS01). The VivaChek™ Ino Sound Bright 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.

Technological Characteristics:

Specification of VivaChek™ Ino Smart Blood Glucose Monitoring System (Model: VGM04):

Feature	Specification
Measurement range	20 to 600 mg/dL
Test Measured	Glucose in fingertip capillary blood
Sample	Fresh capillary whole blood
Sample volume:	0.8 µL
Test time	5 seconds
Power source	Rechargeable 3.7 Volt Lithium Ion battery
Charging current	100mAh, ⎓ Direct current
Battery type	Rechargeable, non-serviceable, 250mAh, 3.7 Volt DC nominal, lithium polymer battery (5V input charge voltage)
Glucose units of measure	The meter is pre-set to milligrams per deciliter (mg/dL)
Memory	Up to 500 records with date and time
Automatic shutoff	2 minutes after last action
Dimensions	83 mm x 52 mm x 18.7 mm
Display size	32mm x 32 mm
Weight	Approximately 53g
Operating temperature	41-113°F
Operating relative humidity	10-90% (non-condensing)
Hematocrit range	20-70%
Data port	Micro USB
Bluetooth	Version 4.1 (syncing with a iPhone for data and time)

Specification of VivaChek™ Ino Sync Blood Glucose Monitoring System (Model: VGM05):

Feature	Specification
Measurement range	20 to 600 mg/dL
Test Measured	Glucose in fingertip capillary blood
Sample	Fresh capillary whole blood
Sample volume:	0.8 µL
Test time	5 seconds
Power source	Rechargeable 3.7 Volt Lithium Ion battery
Charging current	100mAh, ⎓ Direct current
Battery type	Rechargeable, non-serviceable, 250mAh, 3.7 Volt DC nominal, lithium polymer battery (5V input charge voltage)
Glucose units of measure	The meter is pre-set to milligrams per deciliter (mg/dL)

Memory	Up to 500 records with date and time
Automatic shutoff	2 minutes after last action
Dimensions	90.4 mm x 54.5 mm x 27.8 mm
Display size	32mm x 32 mm
Weight	Approximately 53g
Operating temperature	41-113°F
Operating relative humidity	10-90% (non-condensing)
Hematocrit range	20-70%
Data port	Micro USB
Dimensions	90.4 mm x 54.5 mm x 27.8 mm

Specification of VivaChek™ Ino Sound Blood Glucose Monitoring System (Model: VGM09):

Feature	Specification
Measurement range	20 to 600 mg/dL
Test Measured	Glucose in fingertip capillary blood
Sample	Fresh capillary whole blood
Sample volume:	0.8 µL
Test time	5 seconds
Power source	Two AAA LR03 1.5V batteries
Glucose units of measure	The meter is pre-set to milligrams per deciliter (mg/dL)
Memory	Up to 1000 records with date and time
Automatic shutoff	2 minutes after last action
Dimensions	90.4 mm x 54.5 mm x 27.8 mm
Display size	39 mm x 41 mm
Weight	Approximately 63g
Operating temperature	41-113°F
Operating relative humidity	10-90% (non-condensing)
Hematocrit range	20-70%
Data port	Micro USB
Bluetooth	Version 4.1 (syncing with a iPhone for data and time)

Specification of VivaChek™ Ino Plus Blood Glucose Monitoring System (Model: VGM22):

Feature	Specification
Measurement range	20 to 600 mg/dL
Test Measured	Glucose in fingertip capillary blood
Sample	Fresh capillary whole blood

Sample volume:	0.8 µL
Test time	5 seconds
Power source	Two AAA LR03 1.5V batteries
Glucose units of measure	The meter is pre-set to milligrams per deciliter (mg/dL)
Memory	Up to 1000 records with date and time
Automatic shutoff	2 minutes after last action
Dimensions	90.4 mm x 54.5 mm x 27.8 mm
Display size	39 mm x 41 mm
Weight	Approximately 63g
Operating temperature	41-113°F
Operating relative humidity	10-90% (non-condensing)
Hematocrit range	20-70%
Data port	Micro USB
Bluetooth	Version 4.1 (syncing with a iPhone for data and time)

Specification of VivaChek™ Ino Sound Simple Blood Glucose Monitoring System (Model: VGM26):

Feature	Specification
Measurement range	20 to 600 mg/dL
Test Measured	Glucose in fingertip capillary blood
Sample	Fresh capillary whole blood
Sample volume:	0.8 µL
Test time	5 seconds
Power source	Two AAA LR03 1.5V batteries
Glucose units of measure	The meter is pre-set to milligrams per deciliter (mg/dL)
Memory	Up to 1000 records with date and time
Automatic shutoff	2 minutes after last action
Dimensions	90.4 mm x 54.5 mm x 27.8 mm
Display size	39 mm x 41 mm
Weight	Approximately 63g
Operating temperature	41-113°F
Operating relative humidity	10-90% (non-condensing)
Hematocrit range	20-70%

Specification of VivaChek™ Ino Sound Bright Blood Glucose Monitoring System (Model: VGM27):

Feature	Specification

Measurement range	20 to 600 mg/dL
Test Measured	Glucose in fingertip capillary blood
Sample	Fresh capillary whole blood
Sample volume:	0.8 µL
Test time	5 seconds
Power source	Two AAA LR03 1.5V batteries
Glucose units of measure	The meter is pre-set to milligrams per deciliter (mg/dL)
Memory	Up to 1000 records with date and time
Automatic shutoff	2 minutes after last action
Dimensions	90.4 mm x 54.5 mm x 27.8 mm
Display size	39 mm x 41 mm
Weight	Approximately 63g
Operating temperature	41-113°F
Operating relative humidity	10-90% (non-condensing)
Hematocrit range	20-70%

Comparison to Predicate Devices:

The VivaChek™ Ino Smart Blood Glucose Monitoring System (Model: VGM04) is substantially equivalent to VivaChek™ Ino Blood Glucose Monitoring System (K160179)

Features	**VivaChek™ Ino Blood Glucose Monitoring System (K160179)**	**VivaChek™ Ino Smart Blood Glucose Monitoring System (Model: VGM04)**
Similarities		
Assay Method	Glucose oxidase biosensor	Same
Measurement Range	20 to 600 mg/dL	Same
Strip Chemical Composition	Glucose oxidase, Mediator	Same
Test Measured	Glucose in fingertip capillary blood	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	Same
Automatic Shutoff	2 minutes after last action	Same
Minimum Sample Size	0.8µL	Same

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Hematocrit Range	20–70%	Same
Operating Temperature	5–45°C (41–113°F)	Same
Differences		
Alternative Sample Site for Capillary	Palm and forearm in addition to fingertip	None
Meter Memory	Up to 900 records with time and date	Up to 500 records with time and date
Battery Life	12 months or approximately 1,000 tests	Rechargeable
Power Source	Two (2) CR 2032 3.0V coin cell batteries	Rechargeable, non-serviceable, 250mAh, 3.7 Volt DC nominal, lithium polymer battery (5V input charge voltage)
Meter Size	82.5 mm × 52 mm × 18.2 mm	83 mm x 52 mm x 18.7 mm
Meter Weight	Approximately 47g (with battery installed)	Approximately 53g
Bluetooth	None	Yes

The other 5 subject devices (VGM05, VGM09, VGM22, VGM26, VGM27) are substantially equivalent to VivaChek™ Ino Blood Glucose Monitoring System(K160179)

Features	VivaChek™ Ino Blood Glucose Monitoring System(K160179)	VGM04	VGM05	VGM09	VGM22	VGM26	VGM27
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. 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..	Same	Same	Same	Same	Same	Same
Assay Method	Glucose oxidase biosensor	Same	Same	Same	Same	Same	Same
Strip Chemical Composition	Glucose oxidase, Mediator	Same	Same	Same	Same	Same	Same
Test measured	Glucose in fingertip capillary whole blood	Same	Same	Same	Same	Same	Same
Measurement Range	20 to 600 mg/dL	Same	Same	Same	Same	Same	Same
Test Time	5 seconds	Same	Same	Same	Same	Same	Same
Sample Type	Fresh capillary whole blood	Same	Same	Same	Same	Same	Same
Glucose Units of Measure	mg/dL	Same	Same	Same	Same	Same	Same
Operating Relative Humidity	10–90%	Same	Same	Same	Same	Same	Same
Data Port	mini USB	Same	Same	Same	Same	Same	Same
Automatic Shutoff	2 minutes after last action	Same	Same	Same	Same	Same	Same
Minimum Sample Size	0.8μL	Same	Same	Same	Same	Same	Same
Hematocrit Range	20–70%	Same	Same	Same	Same	Same	Same
Operating Temperature	5–45°C (41–113°F)	Same	Same	Same	Same	Same	Same
Alternative Sample Site	Palm and forearm in addition to	None	None	None	None	None	None

for Capillary	fingertip						
Meter Memory	Up to 900 records with time and date	Up to 500 records with time and date	Up to 500 records with time and date	Up to 1000 records with time and date	Up to 1000 records with time and date	Up to 1000 records with time and date	Up to 1000 records with time and date
Battery Life	12 months or approximately 1,000 tests	Rechargeable	Rechargeable	Same	Same	Same	Same
Power Source	Two (2) CR 2032 3.0V coin cell batteries	Rechargeable, non-serviceable, 250mAh, 3.7 Volt DC nominal, lithium polymer battery (5V input charge voltage)	Rechargeable, non-serviceable, 250mAh, 3.7 Volt DC nominal, lithium polymer battery (5V input charge voltage)	Two AAA LR03 1.5V batteries	Two AAA LR03 1.5V batteries	Two AAA LR03 1.5V batteries	Two AAA LR03 1.5V batteries
Meter Size	82.5 mm × 52 mm × 18.2 mm	83 mm x 52 mm x 18.7 mm	82 mm x 54 mm x 23 mm	90.4 mm x 54.5 mm x 27.8 mm	90.4 mm x 54.5 mm x 27.8 mm	90.4 mm x 54.5 mm x 27.8 mm	90.4 mm x 54.5 mm x 27.8 mm
Meter Weight	Approximately 47g (with battery installed)	Approximately 53g	Approximately 53g	Approximately 63g	Approximately 63g	Approximately 63g	Approximately 63g
Bluetooth	None	Yes	Yes	Yes	Yes	None	None
Talking function	None	None	None	Yes	None	Yes	Yes

Laboratory Testing:

The performance characteristics of the VivaChek™ Ino Smart (VGM04), VivaChek™ Ino Sound (VGM09), VivaChek™ Ino Plus (VGM22), and VivaChek™ Ino Sound Simple (VGM26) Blood Glucose Monitoring Systems were evaluated by performing the following studies as below:

No.	Test/Validation Item	Reference	Conclusion
1	Linearity Study	FDA SMBG Guidance	Pass
2	User Evaluation	FDA SMBG Guidance	Pass
3	User Evaluation-Accuracy at Extreme Glucose Values	FDA SMBG Guidance	Pass
4	Accelerated Closed vial Stability Study _Strip with 65^{o}C	FDA SMBG Guidance	Pass
5	Real Time Open Vial stability Study _Strip	FDA SMBG Guidance ISO 23640	In-process
6	Real Time Extended Open Vial stability Study_Strip	FDA SMBG Guidance	Pass
7	Sample Perturbation Study	FDA SMBG Guidance ISO15197:2015	Pass
8	Accelerated Closed vial Stability Study _Control with 65^{o}C	FDA SMBG Guidance	Pass

9	Real Time Open Vial stability Study _Control	FDA SMBG Guidance	Pass
10	Real Time Extend Open Vial stability Study _Control	FDA SMBG Guidance	Pass
11	Hematocrit Effect Study	FDA SMBG Guidance	Pass
12	Sample Volume Study	FDA SMBG Guidance	Pass
13	Intermediate Precision Study	FDA SMBG Guidance	Pass
14	Within-Run Precision Study	FDA SMBG Guidance	Pass
15	Low Battery Study	FDA SMBG Guidance	Pass
16	Altitude Effect Evaluation	FDA SMBG Guidance	Pass
17	Operating Conditions Evaluation	FDA SMBG Guidance	Pass
18	Shipping Study _test strip	FDA SMBG Guidance	Pass
19	Shipping Study_Control	FDA SMBG Guidance	Pass
20	Control Range Assignment	FDA SMBG Guidance	Pass
21	Oxygen Interference Study	FDA SMBG Guidance	Pass
22	Intermittent Sampling Study	FDA SMBG Guidance	Pass
23	Interference Agents Study	FDA SMBG Guidance ISO15197:2015	Pass
24	Real Time Closed Vial Stability Study _Strip Study	FDA SMBG Guidance ISO 23640	In-process
25	Real Time Closed Vial Stability Study _Control Study	FDA SMBG Guidance	Pass
26	Meter Robustness Study	FDA SMBG Guidance	Pass
27	Meter Vibration Test	FDA SMBG Guidance	Pass
28	Meter Shock Test	FDA SMBG Guidance	Pass
29	Meter Environmental Temperature Test	FDA SMBG Guidance	Pass
30	Meter Bluetooth Communication Distance Test	Design Specification & FCC Rule Part 15 Subpart C (Section 15.247)	Pass
31	Meter Talking Features (Functionality) Test	Design specification	Pass
32	Error Codes Test	Design specification	Pass

33	Testing with Used Test Strips	Design specification	Pass
34	Meter Software Documentation	Guidance for the Content of Premarket Submission for Software Contained in Medical Devices	Pass
35	GlucoWell App Software Documentation	Guidance for the Content of Premarket Submission for Software Contained in Medical Devices	Pass
36	Electromagnetic Compatibility and Electrical Safety	IEC 60601-1- 2; IEC 60601-1; IEC 60601-1-11	Pass
37	Cybersecurity (for VGM04, 05, 09, 22)	Cybersecurity for Networked Medical Devices Containing OTS Software; Content of Premarket Submission for Management of Cybersecurity in Medical Devices	Pass

To confirm bluetooth and talking functionalities have not brought any unexpected functional failure or adverse effect, validation on these functionalities were also conducted, accepted and summarized in above table.

Discussion of Clinical Study:

Clinical (user evaluation) studies were conducted with intended user, lay persons using the VivaChek™ Ino Smart (VGM04), VivaChek™ Ino Sound (VGM09), VivaChek™ Ino Plus (VGM22), and VivaChek™ Ino Sound Simple (VGM26) Blood Glucose Monitoring Systems. The study data were presented evaluating the system accuracy of the VivaChek™ Ino Smart (VGM04), VivaChek™ Ino Sound (VGM09), VivaChek™ Ino Plus (VGM22), and VivaChek™ Ino Sound Simple (VGM26) Blood Glucose Monitoring Systems per the VivaChek User Evaluation Study Protocols for these Blood Glucose Monitoring Systems. Study results indicated that non-professional, inexperienced lay persons were able to obtain blood glucose readings when using the VivaChek™ Ino Smart (VGM04), VivaChek™ Ino Sound (VGM09), VivaChek™ Ino Plus (VGM22), and VivaChek™ Ino Sound Simple (VGM26) Blood Glucose Monitoring Systems. In addition, the participated 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 Smart (VGM04), VivaChek™ Ino

Sound (VGM09), VivaChek™ Ino Plus (VGM22), and VivaChek™ Ino Sound Simple (VGM26) Blood Glucose Monitoring Systems.

The VivaChek™ Ino Sync (VGM05) has the same intended use, fundamental scientific technology and performance characteristics as VivaChek™ Ino Smart (VGM04). Therefore, the safety, effectiveness and performance are same as the predicate device.

The VivaChek™ Ino Sound Bright (VGM27) has the same intended use, fundamental scientific technology and performance characteristics as VivaChek™ Ino Sound Simple (VGM26). Therefore, the safety, effectiveness and performance are same as the predicate device.

Conclusion:

The laboratory testing and user evaluation study results demonstrate that the VivaChek™ Ino Smart (VGM04), VivaChek™ Ino Sound (VGM09), VivaChek™ Ino Plus (VGM22), and VivaChek™ Ino Sound Simple(VGM26) Blood Glucose Monitoring System are safe, effective and easy-to-use. It also demonstrates that the VivaChek™ Ino Smart (VGM04), VivaChek™ Ino Sound (VGM09), VivaChek™ Ino Plus (VGM22), and VivaChek™ Ino Sound Simple (VGM26) Blood Smart Glucose Monitoring Systems meet FDA SMBG Guidance and are substantially equivalent to the VivaChek™ Ino Blood Glucose Monitoring System (K160179). Based on same intended use and technology characteristics, and the test results on user friendly functionalities on bluetooth or talking, the other two subject devices (VGM05, VGM27) are also substantially equivalent to the predicate device.