510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K260687

B Applicant

VivaChek Biotech (Hangzhou) Co., Ltd.

C Proprietary and Established Names

VivaChek Blood Glucose and β-Ketone Dual BLE Monitoring System
VivaChek Blood Glucose and β-Ketone Dual Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry
JIN	Class I, meets the limitation of exemption 21 CFR 862.9(c)(5)	21 CFR 862.1435 - Ketones (nonquantitative) test system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New devices

B Measurand:

Glucose and β-hydroxybutyrate in capillary whole blood obtained from the fingertip

C Type of Test:

Quantitative amperometric detection of glucose using glucose dehydrogenase/FAD and β-hydroxybutyrate using 3-hydroxybutyrate dehydrogenase/NAD

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

VivaChek Blood Glucose and β-Ketone Dual BLE Monitoring System is comprised of VivaChek Blood Glucose and β-Ketone Dual BLE Meter and VivaChek Blood Glucose and β-Ketone Dual Test Strips. The VivaChek Blood Glucose and β-Ketone Dual BLE Monitoring System is intended to quantitatively measure the glucose concentration and β-Ketone 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 Blood Glucose and β-Ketone Dual Monitoring System is comprised of VivaChek Blood Glucose and β-Ketone Dual Meter and VivaChek Blood Glucose and β-Ketone Dual Test Strips. The VivaChek Blood Glucose and β-Ketone Dual Monitoring System is intended to quantitatively measure the glucose concentration and β-Ketone 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.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

- For in vitro diagnostic use only
- For single patient use only
- Not for neonatal use.
- Not for screening for or diagnosis of diabetes mellitus.
- Not for Alternative Site Testing (AST).
- Do not use the system above 10413 ft (3174 meters) in altitude.
- This meter is not intended for use in healthcare or assisted-use settings, such as hospitals, physician offices, or long-term care facilities. It has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures.
- Use of this meter on multiple patients may lead to transmission of Human Immunodeficiency Virus, Hepatitis C Virus, Hepatitis B Virus, or other bloodborne pathogens.

- Not for use on~~the specific patients listed in table below~~:
    - Critically ill patients
    - Patients in shock
    - Patients in a hyperglycemic- hyperosmolar state with or without ketosis
    - Patients with severe dehydration
    - Patients with severe hypotension

D Special Instrument Requirements:

VivaChek Blood Glucose and β -Ketone Dual BLE Monitoring Meter
VivaChek Blood Glucose and β -Ketone Dual Monitoring Meter

IV Device/System Characteristics:

A Device Description:

VivaChek Blood Glucose and β-Ketone Dual and Dual BLE Monitoring Systems are comprised of VivaChek Blood Glucose and β-Ketone Dual or Dual BLE Meter and VivaChek Blood Glucose and β-Ketone Dual Test Strips. This system is designed to quantitatively measure both glucose and β-ketone (β -hydroxybutyrate) concentrations in fresh capillary whole blood samples drawn from fingertips. The test strip measures both analytes simultaneously from a single blood sample. Both glucose and β-ketone results are displayed on the meter screen simultaneously after each test. The Dual and Dual BLE meters differ only in the addition of Bluetooth Low Energy connectivity to the Dual BLE meter for wireless transmission of test results to the optional VivaChek GlucoKet App.

B Principle of Operation:

VivaChek Blood Glucose and β-Ketone Dual and Dual BLE Monitoring Systems are designed to quantitatively measure both glucose and β-Ketone concentrations in a single sample of fresh capillary whole blood. The glucose measurement and β-Ketone measurements are achieved by using an amperometric detection method. The blood sample is pulled into the tip of the test strip through capillary action. Glucose in the sample reacts with glucose dehydrogenase and β-Ketone (β -hydroxybutyrate) in the sample reacts with β -hydroxybutyrate dehydrogenase. The magnitude of the generated electrical current is proportional to the glucose and β-Ketone amounts in the sample. After the reaction time, the glucose and β-Ketone concentration values are reported in plasma equivalents and are displayed on meter.

C Instrument Description Information:

1. Instrument Name:

   VivaChek Blood Glucose and β-Ketone Dual BLE Monitoring Meter
   VivaChek Blood Glucose and β-Ketone Dual Monitoring Meter

2. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected

3. Specimen Sampling and Handling:

   Samples are to be tested immediately upon collection.

4. Calibration:

   The meters do not require calibration or coding by the user.

5. Quality Control:

   The sponsor manufactures VivaChek Glucose and β-Ketone Dual Control Solutions available in three (3) levels (1, 2, and 3). Each control solution level contains both glucose and β-ketone at varying concentrations: Control Solution 1 represents low concentrations of both analytes, Control Solution 2 represents mid-range concentrations, and Control Solution 3 represents high concentrations. When the user runs each control solution level, they obtain both glucose and β-ketone results simultaneously. Each test strip vial includes the expected control ranges for both analytes at each level. The user is instructed to compare the control test results with the expected control ranges printed on the test strip vial label. Users are given instructions on when to conduct control solution testing and to call customer service if repeat testing with control material is out of range. The meter automatically recognizes control solution and marks control solution results accordingly; control solution results are not included in the patient result averages.

V Substantial Equivalence Information:

A Predicate Device Name(s):

FORA ADVANCED GD-40 Blood Glucose and β-Ketone Monitoring System

B Predicate 510(k) Number(s):

K161738

C Comparison with Predicate(s):

Device & Predicate Device(s):	K260687	K161738
Device Trade Name	VivaChek Blood Glucose and β -Ketone Dual BLE Monitoring System VivaChek Blood Glucose and β -Ketone	FORA ADVANCED GD-40 Blood Glucose and β-Ketone Monitoring System

	Dual Monitoring System	
General Device Characteristic Similarities		
Intended Use/Indications For Use	It is intended for the quantitative measurement of glucose in mg/dL and β-ketone in mmole/L in fresh capillary whole blood from the finger. For single-patient use.	Same
Glucose Measuring Range	20 – 600 mg/dL	Same
β-Ketone Measuring Range	0.1 - 8.0 mmol/L	Same
General Device Characteristic Differences		
Operating Condition	45 – 113 °F (7 - 45 °C), 10 - 90% RH	50 – 104 °F(10 – 40 °C), 10 - 85% RH
Hematocrit Range	20 - 65%	20 - 70%
Sample Volume	1.6 µL	Blood glucose: 0.9 µL; Blood β-ketone: 1.0 µL
Test Time	Glucose: 5 seconds, β-ketone: 7 seconds	Glucose: 5 seconds β-ketone: 10 seconds
Meter Memory	300 records	1000 records

VI Standards/Guidance Documents Referenced:

IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION
Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements [Including: Corrigendum 1 (2019)]

FDA Guidance Document: Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use, issued September 29, 2020

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

The sponsor conducted the analytical and clinical studies discussed below using the VivaChek Blood Glucose and β-Ketone Dual BLE Monitoring System to represent both candidate systems (with and without Bluetooth Low Energy capability). The differences between the two systems is limited to the presence or absence of BLE functionality. Therefore, the studies using the BLE meter are representative of the performance of both device systems in this 510(k) submission.

1. Precision/Reproducibility:

Glucose:

A glucose within-run precision (repeatability) study using 3 lots of VivaChek Blood Glucose and β-Ketone Dual Test Strips was performed. Venous blood was spiked to 5 concentrations (30-50, 51-110, 111-150, 151-250, 251-400 mg/dL). For each sample concentration, 10 meters were used, with 10 measurements taken by each meter (i.e., 100 measurements per concentration per lot). Results are summarized below:

Venous Blood Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV
Level 1 (30-50)	Lot 1	100	45.3	1.7	3.8%
	Lot 2	100	45.4	1.8	3.9%
	Lot 3	100	45.6	1.7	3.7%
	Combined	300	45.4	1.7	3.8%
Level 2 (51-110)	Lot 1	100	70.3	2	2.8%
	Lot 2	100	70.3	2.1	3.0%
	Lot 3	100	70.4	2.1	3.0%
	Combined	300	70.3	2.1	2.9%
Level 3 (111-150)	Lot 1	100	135.8	3.6	2.7%
	Lot 2	100	135.8	3.5	2.6%
	Lot 3	100	136.6	3.3	2.4%
	Combined	300	136	3.5	2.6%
Level 4 (151-250)	Lot 1	100	207.7	5.3	2.6%
	Lot 2	100	205.5	5.6	2.7%
	Lot 3	100	205.7	5.7	2.8%
	Combined	300	206.3	5.6	2.7%
Level 5 (251-400)	Lot 1	100	326.4	8.3	2.5%
	Lot 2	100	324.9	8.3	2.6%
	Lot 3	100	325.3	7.9	2.4%
	Combined	300	325.5	8.2	2.5%

Glucose intermediate precision of the VivaChek Blood Glucose and β-Ketone Dual BLE Monitoring System was evaluated using 5 levels of glucose control solutions (30-50, 51-110, 111-150, 151-250, 251-400 mg/dL) using 3 lots of VivaChek Blood Glucose and β-Ketone Dual Test Strips. The tests were conducted with 10 meters, one measurement per meter per day at the five different glucose ranges, for ten days for a total of 300 glucose results per each glucose level. Results are summarized below:

Glucose Control Levels (mg/dL)	Strip lot	N	Mean (mg/dL)	SD (mg/dL)	CV
L1 (30-50)	Lot 1	100	38.6	1.4	3.8%
	Lot 2	100	38.4	1.4	3.7%
	Lot 3	100	38.4	1.5	3.8%
	Combined	300	38.5	1.4	3.8%
L2 (51-110)	Lot 1	100	72.8	1.9	2.7%
	Lot 2	100	72.5	2.1	2.9%
	Lot 3	100	72.6	2	2.8%
	Combined	300	72.6	2	2.8%
L3 (111-150)	Lot 1	100	135.3	3.1	2.3%
	Lot 2	100	134.9	3.4	2.5%
	Lot 3	100	134.7	3.2	2.4%
	Combined	300	135	3.2	2.4%
L4 (151-250)	Lot 1	100	215.4	5.4	2.5%
	Lot 2	100	214.8	5.5	2.6%
	Lot 3	100	215.5	5.2	2.4%
	Combined	300	215.3	5.4	2.5%
L5 (251-400)	Lot 1	100	364.5	9.4	2.6%
	Lot 2	100	366.3	9.5	2.6%
	Lot 3	100	365.3	9.1	2.5%
	Combined	300	365.5	9.3	2.6%

Ketone:

The sponsor performed a ketone repeatability (within-run) precision study using 3 lots of VivaChek Blood Glucose and β-Ketone Dual Test Strips. Venous blood samples that were spiked to 5 ketone concentrations (0.1-1.0, 1.1-2.0, 2.1-3.0, 4.1-5.0, 6.1-7.0 mmol/L) were used. For each sample concentration, 10 meters were used, with 10 measurements taken by each meter (i.e., 100 measurements per concentration per lot). Results are summarized below:

Venous Blood Ketone Level (mmol/L)	Lot	N	Mean (mmol/L)	SD (mmol/L)	CV (%)
Level 1 (0.1-1.0)	Lot 1	100	0.6	0.06	9.2%
	Lot 2	100	0.58	0.05	9.3%
	Lot 3	100	0.59	0.06	9.5%
	Combined	300	0.59	0.06	9.4%
Level 2 (1.1-2.0)	Lot 1	100	1.43	0.06	3.9%
	Lot 2	100	1.42	0.06	4.1%
	Lot 3	100	1.44	0.06	3.9%
	Combined	300	1.43	0.06	4.0%
Level 3 (2.1-3.0)	Lot 1	100	2.45	0.08	3.3%
	Lot 2	100	2.47	0.08	3.2%
	Lot 3	100	2.45	0.08	3.4%
	Combined	300	2.46	0.08	3.3%
Level 4 (4.1-5.0)	Lot 1	100	4.7	0.15	3.2%
	Lot 2	100	4.68	0.14	3.0%
	Lot 3	100	4.67	0.15	3.2%
	Combined	300	4.68	0.15	3.2%
Level 5 (6.1-7.0)	Lot 1	100	6.57	0.21	3.2%
	Lot 2	100	6.58	0.22	3.4%
	Lot 3	100	6.63	0.21	3.2%
	Combined	300	6.59	0.22	3.3%

Ketone intermediate precision was evaluated using five levels of β-ketone control solutions (0.1-1.0, 1.1-2.0, 2.1-3.0, 4.1-5.0, and 6.1-7.0 mmol/L). Testing was conducted over 10 days with three test strip lots and 10 meters. For each control solution 10 replicates were taken each day resulting in 100 individual measurements per level:

Venous Blood Ketone Level (mmol/L)	Lot	N	Mean (mmol/L)	SD (mmol/L)	CV (%)
Level 1 (0.1-1.0)	Lot 1	100	0.6	0.05	8.5%
	Lot 2	100	0.61	0.05	8.4%
	Lot 3	100	0.61	0.05	8.6%
	Combined	300	0.6	0.05	8.5%
Level 2 (1.1-2.0)	Lot 1	100	1.49	0.06	3.8%
	Lot 2	100	1.5	0.05	3.6%
	Lot 3	100	1.49	0.06	3.8%
	Combined	300	1.49	0.06	3.7%
Level 3 (2.1-3.0)	Lot 1	100	2.51	0.07	2.7%
	Lot 2	100	2.49	0.07	2.9%
	Lot 3	100	2.51	0.07	2.8%
	Combined	300	2.5	0.07	2.8%
Level 4 (4.1-5.0)	Lot 1	100	4.49	0.13	2.9%
	Lot 2	100	4.49	0.14	3.1%

Venous Blood Ketone Level (mmol/L)	Lot	N	Mean (mmol/L)	SD (mmol/L)	CV (%)
	Lot 3	100	4.52	0.13	2.8%
	Combined	300	4.5	0.13	2.9%
Level 5 (6.1-7.0)	Lot 1	100	6.53	0.18	2.8%
	Lot 2	100	6.49	0.17	2.6%
	Lot 3	100	6.5	0.18	2.7%
	Combined	300	6.5	0.18	2.7%

Additional bench studies were conducted to assess the potential impact of various combinations of extreme glucose and ketone concentrations, under different conditions and hematocrit concentrations on both glucose and ketone results. Refer to Section E below for additional detail.

2. Linearity:

Glucose Linearity

The linearity of glucose measurements was evaluated using venous whole blood samples adjusted to eleven glucose concentrations ranging from 22.6 to 583.3 mg/dL (22.6, 78.3, 136.5, 198.5, 250.0, 309.0, 365.5, 433.0, 484.5, 539.0, and 583.5 mg/dL as measured by the comparator method). Four replicates with three test strip lots per glucose concentration were assessed. The summary of the linear regression analysis for each lot was as follows:

Lot #	Slope	y-intercept	R^2 value
Lot 1	0.995	0.931	0.998
Lot 2	0.9903	2.1825	0.9978
Lot 3	0.9938	1.4004	0.9976
All 3 Strip Lots	0.993	1.5046	0.9978

The results of the study support the sponsor's claimed glucose measuring range of 20-600 mg/dL. If a sample result is less than 20 mg/dL glucose, the result is flagged by the meter as "LO". If a sample result exceeds 600 mg/dL glucose, the result is flagged by the meter as "HI". The "LO" and "HI" functions were validated by the sponsor and were demonstrated to function as intended.

Ketone Linearity

Linearity of ketone measurements was evaluated using venous whole blood samples adjusted to eleven ketone concentrations ranging from 0.12 to 7.76 mmol/L (0.12, 0.35, 0.65, 1.16, 1.83, 2.52, 3.32, 4.31, 5.23, 6.53, and 7.76 mmol/L as measured by the comparator method). Three test strip lots were used for the linearity evaluation study.). Four replicates with three test strip lots per ketone concentration were assessed. The summary of the linear regression analysis for each lot was as follows:

Lot #	Slope	y-intercept	R^2 value
Lot 1	0.9984	0.0076	0.9972
Lot 2	0.9895	0.0349	0.9973

Lot #	Slope	y-intercept	R^2 value
Lot 3	0.9921	0.0088	0.9978
All 3 Strip Lots	0.9951	0.0151	0.9975

The results of the study support the sponsor's claimed β-ketone measuring range of 0.1-8.0 mmol/L. If a sample result is less than 0.1 mmol/L ketone, the result is flagged by the meter as "< 0.1 mmol/L". If a sample result exceeds 8.0 mmol/L ketone, the result is flagged by the meter as "> 8.0 mmol/L". The ""< 0.1 mmol/L" and ""> 8.0 mmol/L" functions were validated by the sponsor and were demonstrated to function as intended.

3. Analytical Specificity/Interference:

To evaluate the potential interference exogenous and endogenous substances on both glucose and β-ketone measurement functions, venous whole blood samples at three concentration levels of glucose (50-70 mg/dL, 110-130 mg/dL, and 225-270 mg/dL) or β-ketone (0.1-1.0 mmol/L, 1.1-2.0 mmol/L, and 3.1-4.0 mmol/L) were assessed.

Each sample was divided into a control sample (with no added interferent) and a test sample (with added potential interferent). Results from the test samples obtained using the candidate system were compared to the results obtained with the control samples using the candidate system. The highest tested concentration for each substance at which no significant interference was observed (defined by the sponsor as bias within ±4 mg/dL for glucose concentrations < 75 mg/dL and ±8% for glucose concentrations ≥ 75 mg/dL, and bias within ±0.20 mmol/L for β-ketone concentrations < 1.5 mmol/L and ±10% for β-ketone concentrations ≥ 1.5 mmol/L) for either glucose or ketone measurement is summarized in the following table:

Substance	Highest concentration at which no significant interference is observed
Acetaminophen	20 mg/dL
Acetoacetate	21 mg/dL
Acetone	70 mg/dL
Acetylsalicylic Acid	50 mg/dL
Acyclovir	3.1 mg/dL
Allopurinol	5 mg/dL
Amitriptylline	0.27 mg/dL
Amoxicillin	12.5 mg/dL
Ampicillin	5 mg/dL
Ascorbic Acid	6 mg/dL
Aspirin	60 mg/dL
Atenolol	10 mg/dL
Bicarbonate	336 mg/dL
Bilirubin (Conjugated)	50 mg/dL
Bilirubin (Unconjugated)	40 mg/dL
Caffeine	10 mg/dL

Substance	Highest concentration at which no significant interference is observed
Calcium	5 mmol/L
Captopril	500 mg/dL
Ceftriaxone	250 mg/dL
Chloride	140 mmol/L
Cholic Acid	6 mg/dL
Cholesterol	500 mg/dL
Clonidine	2 mg/dL
Creatinine	30 mg/dL
Digoxin	0.16 mg/dL
Diphenhydramine	1 mg/dL
Dopamine	1.25 mg/dL
EDTA	0.1 mg/dL
Enalapril	0.15 mg/dL
Ephedrine HCl	60 mg/dL
Erythromycin	20 mg/dL
Estrone	0.1 mg/dL
Famotidine	0.13 mg/dL
Fluoxetine	0.8 mg/dL
Folic Acid	13.3 mg/dL
Fructose	1000 mg/dL
Furosemide	2 mg/dL
Galactose	1000 mg/dL
Gamma-Globulin	12000 mg/dL
Gentisic Acid	2 mg/dL
Glyburide	1.07 mg/dL
Glycerol	1000 mg/dL
Hemoglobin	1000 mg/dL
Heparin	300 IU/dL
Ibuprofen	55 mg/dL
Icodextrin	2000 mg/dL
Isomalt	1000 mg/dL
Lactitol	1000 mg/dL
Lactose	1000 mg/dL
Levo-Dopa (L-Dopa)	0.75 mg/dL
Lidocaine	6 mg/dL
Magnesium	5 mmol/L
Maltitol	1000 mg/dL
Maltose	1000 mg/dL
Mannitol	1800 mg/dL
Mannose	1.15 mg/dL

Substance	Highest concentration at which no significant interference is observed
Metaproterol	1.81 mg/dL
Metformin HCl	50 mg/dL
Methyldopa	2 mg/dL
Metoprolol	0.3 mg/dL
N-Acetylcysteine	2.59 mg/dL
Naproxen	100 mg/dL
Nifedipine	0.17 mg/dL
Nortriptyline	0.15 mg/dL
Penicillin	12 mg/dL
Phenytoin	10 mg/dL
Piroxicam	5 mg/dL
Potassium	10 mmol/L
Pralidoxime Iodide	5 mg/dL
Reduced Glutathione	30 mg/dL
Salicylic Acid	60 mg/dL
Sodium	200 mmol/L
Sorbitol	1000 mg/dL
Sulfamethoxazole	120 mg/dL
Sulfate	5 mmol/L
Tetracycline	30 mg/dL
Theophylline	25 mg/dL
Terfenadine	0.45 mg/dL
Tolazamide	9 mg/dL
Tolbutamide	72 mg/dL
Triglycerides	3000 mg/dL
Trimethoprim	12.5 mg/dL
Urea	600 mg/dL
Uric Acid	24 mg/dL
Vancomycin	25 mg/dL
Verapamil	0.45 mg/dL
Vitamin E	20 mg/dL
Warfarin	2 mg/dL
Xylitol	1000 mg/dL
Xylose	1000 mg/dL

All substances were tested at the concentrations listed above and demonstrated no significant interference with either glucose or β-ketone measurements according to the predefined acceptance criteria.

In addition, to assess the impact of pH changes on device performance, pH interference was evaluated at two levels: pH 7.07 (representing severe acidosis as observed in DKA patients)

and pH 7.31 (representing mild acidosis at the lower end of the normal physiological range). Testing was conducted using venous whole blood samples at three glucose and β-ketone concentration levels (50-70 mg/dL and 0.1-1.0 mmol/L; 110–130 mg/dL and 1.1–2.0 mmol/L; 225–270 mg/dL glucose and 3.1–4.0 mmol/L β-ketone) across 10 meters and three test strip lots. Results were compared results from a control sample at normal pH and demonstrated no significant impact of pH on either glucose or β-ketone measurements.

4. Detection Limit and Assay Reportable Range:

   20 - 600 mg/dL for glucose
   0.1 - 8.0 mmol/L for ketone

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Glucose Traceability
   The system reports plasma-equivalent glucose values and is calibrated using the YSI 2900C Biochemistry Analyzer, which is traceable to NIST SRM 917d glucose reference material.

   β-Ketone Traceability
   The system reports plasma-equivalent ketone values that are traceable to commercially available D-3 Hydroxybutyrate calibrator material.

   Stability:

   Accelerated and real-time closed-vial and open-vial stability study protocols and acceptance criteria were reviewed and found acceptable to support the sponsor's claimed 24-month closed-vial shelf life and 6-month open-vial use claim for the VivaChek Blood Glucose and β-Ketone Test Strips when stored at 36–86°F (2–30°C) and 10–90% relative humidity.

6. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable.

2. Matrix Comparison:

   Not applicable. The device is only intended for use with fresh capillary whole blood from a fingerstick.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

Not applicable.

3. Clinical Cut-Off

Not applicable.

4. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Method Comparison/Lay User Performance Study

Glucose

A total of 351 lay-user participants obtained their own fingerstick samples and both glucose and ketone results using only the system components and instructions provided in the labeling. Three glucose test strip lots were used for the study. The glucose concentrations of the participant samples ranged from 61.7 to 371 mg/dL as measured by the comparator method (YSI 2900C Biochemistry Analyzer). The study included 12 unaltered samples with blood glucose concentrations < 80 mg/dL and 36 unaltered samples with blood glucose concentration >250 mg/dL.

The β-ketone concentrations obtained by the participant samples ranged from 0.07 to 1.81 mmol/L as measured by the comparator method (Randox RANBUT D-3-Hydroxybutyrate Assay run on the Randox RX Imola Chemistry Analyzer).

The glucose results obtained by the participants using the candidate device were compared to results obtained using the comparator method and summarized in the table below:

Within ±5%	Within ±10%	Within ±15%	Within ±20%
219/351 (62.4%)	334/351 (95.2%)	351/351 (100%)	351/351 (100%)

Regression analysis results: $y = 0.9912x + 1.3505$, $R^2 = 0.9734$

Ketone

The β-ketone results from the same 351 lay user participants using the candidate device were compared to the results obtained from the comparator method (Randox RANBUT D-3-Hydroxybutyrate Assay run on the Randox RX Imola Chemistry Analyzer; 0.07-1.81 mmol/L) and are summarized in the tables below:

For all β-ketone concentrations <1.5 mmol/L		
Within ±0.15 mmol/L	Within ±0.225 mmol/L	Within ±0.30 mmol/L
330/345 (95.7%)	344/345 (99.7%)	345/345 (100%)

For β-ketone concentrations ≥1.5 mmol/L		
Within ±10%	Within ±15%	Within ±20%
5/6 (83.3%)	6/6 (100%)	6/6 (100%)

Regression analysis results: $y = 0.9890x + 0.0074$; $R^2 = 0.9621$

Usability Assessment:
A usability evaluation was conducted to assess the ability of intended users to understand the labeling and operate the VivaChek Blood Glucose and β-Ketone Dual BLE Monitoring System. The study demonstrated that participants were able to understand the labeling, use the VivaChek Blood Glucose and β-Ketone Dual BLE Monitoring System, and interpret testing results and error messages without assistance.

Readability
A Flesch-Kincaid readability assessment was conducted on the user manuals and test strip insert demonstrating that the labeling was written at an 8th grade reading level or less.

Supplemental Method Comparison Study
To address the limited number of samples with both high glucose and high ketone levels in the lay user study, the sponsor conducted a small supplemental study with native patient capillary fingertip samples. The samples contained both elevated glucose and elevated β-ketone concentrations. Glucose results were compared to results obtained from the glucose comparator and β-ketone results were compared to result obtained from the β-ketone comparator. The results demonstrated that combinations of high glucose and high ketone concentrations did not significantly impact the accuracy of either glucose or β-ketone results.

Accuracy at extreme glucose and ketone concentrations:
An additional study was conducted to evaluate glucose and β-ketone accuracy performance with altered capillary fingerstick samples with extreme glucose and ketone concentrations and 3 test strip lots. Fifty (50) samples were glycolyzed to achieve samples with glucose concentrations less than 80 mg/dL (range: 21.7-79.5 mg/dL). Glucose results from these samples using the candidate device were compared to the glucose comparator method. Fifty (50) samples were spiked to achieve glucose concentrations greater than 250 mg/dL (258-593 mg/dL) and β-ketone concentrations ≥1.5 mmol/L (1.63-7.8 mmol/L). Glucose and β-ketone results from the candidate device were compared to results obtained using the glucose and the ketone comparator. Results are summarized in the tables below:

Glucose results

For glucose concentration <80 mg/dL			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
60% (30/50)	90% (45/50)	100% (50/50)	100% (50/50)
For glucose concentration >250 mg/dL			
66% (33/50)	94% (47/50)	100% (50/50)	100% (50/50)

Ketone results

For β-ketone concentrations >1.5 mmol/L			
Within ±5%	Within ±10%	Within ±15%	Within ±20%
58% (29/50)	88% (44/50)	100% (50/50)	100% (50/50)

See section E below for additional bench studies conducted to assess the potential impact of various combinations of extreme glucose and ketone concentrations, operating conditions and hematocrit concentrations on both glucose and ketone results.

D Expected Values/Reference Range:

The sponsors included the following in the labeling:

Glucose
The ideal ranges for adults without diabetes are:
- Under 100 mg/dL before meals.
- Under 140 mg/dL after meals.

American Diabetes Association, Standard of Medical Care in Diabetes 2020, Vol. 43 (Suppl. 1).

Ketone
Based on published literature, the sponsor included < 0.6 mmol/L as the expected value for ketones and cites the following reference:

Evans K. Diabetic ketoacidosis: update on management. Clin Med (Lond). 2019 Sep; 19 (5): 396-398.

E Other Supportive Instrument Performance Characteristics Data:

The sponsor conducted an additional bench study to evaluate the potential impact of various combinations of extreme glucose and ketone concentrations, under different conditions and hematocrit concentrations on both glucose and ketone results. The study assessed venous whole blood samples prepared at four glucose concentration levels (50–70, 110–130, 225–270, and 500–600 mg/dL) at each of four β-ketone concentration ranges (~0.6, ~1.5, ~3.0, and ~7.0 mmol/L). The samples were assessed in replicates of 30 under each of the conditions. Each analyte combination was tested in replicates of 30 and three test strip lots. Glucose and β-ketone results were compared to results from the respective glucose and β-ketone comparator methods. The SDs/%CVs were calculated from the replicate measurements for each analyte combination. The results demonstrated that various analyte combinations did not significantly impact either glucose or β-ketone measurement accuracy or precision.

Hematocrit
The effect of different hematocrit levels was evaluated using venous whole blood samples with hematocrit levels of 20-65% (20, 25, 31, 35, 42, 49, 55, 61, and 65%). The same blood samples contained both glucose and β-ketone at five concentration levels each: glucose levels of 30-50, 51-110, 111-150, 151-250, and 251-400 mg/dL, and β-ketone levels of 0.1-1.0, 1.1-2.0, 2.1-3.0, 4.1-5.0, and 6.1-7.0 mmol/L. Glucose and β-ketone results from the candidate system were compared to results obtained using the respective comparator methods and to the candidate system results from samples with normal hematocrit (~42%). The results demonstrated acceptable performance across the claimed hematocrit range of 20-65%.

System Operating Conditions

The effect of different operating conditions was evaluated using venous whole blood samples that were spiked to contain both glucose (60-70, 100-120, and 300-400 mg/dL) and β-ketone (0.1-1.0, 1.1-2.0, and 3.1-4.0 mmol/L) concentrations. Candidate system results were obtained at the following temperature and relative humidity (RH) combinations: low temperature/low humidity (43°F and 8% RH), low temperature/high humidity (43°F and 92% RH), high temperature/low humidity (115°F and 8% RH), and high temperature/high humidity (115°F and 92% RH). The results were compared to candidate system results obtained at nominal conditions (73.4°F/40% RH): The results support the operating condition claims in the labeling of 45-113°F and relative humidity of 10% to 90%.

Sample Volume

The sponsor performed a study to support the claimed minimum sample volume of 1.6 µL. Venous whole blood samples with three levels of glucose concentrations (approximately 55, 115, and 230 mg/dL) and three levels of β-ketone concentrations (approximately 0.66, 1.46, and 3.55 mmol/L) were tested at three sample volumes (0.8, 1.2, and 1.6 µL) using 3 lots of test strips. The results of the study support the claimed sample volume of 1.6 µL and demonstrate that the insufficient sample volume error message functions as intended.

Infection Control

The device systems are intended for single-patient use only. Disinfection efficacy studies were performed on the external materials comprising the meter by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Clorox™ Healthcare Bleach Germicidal Wipes (EPA Registration No. 67619-12). A robustness study was also conducted by the sponsor demonstrating that there was no change in glucose or ketone performance or in the external materials of the meter after 608 cleaning and disinfection cycles using the Clorox™ Healthcare Bleach Germicidal Wipes. The robustness studies were designed to simulate 5 years of single-patient device use.

Flex Studies

The following additional flex studies were performed with the VivaChek Blood Glucose and β-Ketone Dual BLE Monitoring System: shipping and handling simulation, low battery effect, intermittent sampling, sample perturbation, incorrect strip insertion, testing with used test strips, and test strip early removal. Both glucose and β-ketone measurements were assessed across these flex studies. The testing performed demonstrated that the device is robust under these expected use conditions.

Electrical Safety and EMC Testing

The sponsor provided documentation certifying that acceptable electrical safety and electromagnetic compatibility (EMC) testing had been performed, and the system was found to be compliant.

Software and Cybersecurity

Software and cybersecurity documentation was reviewed and found to be acceptable.

Test Strip Lot Release Protocol

Glucose test strip lot release protocols and criteria were reviewed and found to be acceptable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.