510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K192957

B Applicant

Vivachek Biotech (Hangzhou) Co., Ltd

C Proprietary and Established Names

VivaChek™ Blood Glucose and β-Ketone Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
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:

Modification to exterior of a previously cleared blood glucose meter and addition of β-ketone measurement function

B Measurand:

β-Ketone, as beta-hydroxybutyrate, in fingertip capillary whole blood

C Type of Test:

Quantitative amperometry, β-Ketone (beta-hydroxybutyrate)

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 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.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

For single-patient use only. Not for multiple patient use.
Very high (above 65%) and very low (below 20%) hematocrit levels can cause false results. Talk to your healthcare professional to find out your hematocrit level.
The effect of oxygen therapy on the results of this system has not been studied.
Severe dehydration (excessive water loss) may cause inaccurate results.
Not for neonatal use.
Not for use on patients with critical illness.
Not for use in hypotensive individuals or on patients in shock or in a hyperosmolar state.
Not for screening or diagnosis of diabetes.
Do not use the system at altitudes above 13123ft (4000 meters) above sea level for testing.
Do not use when humidity is higher than 90% and lower than 10%, as extremes in humidity may affect results.
For in vitro diagnostic use only.
The meter is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because 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 device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

D Special Instrument Requirements:

VivaChek™ Blood Glucose and β-Ketone Meter (VGM200)

IV Device/System Characteristics:

A Device Description:

VivaChek™ Blood Glucose and β-Ketone Monitoring System consists of a the VivaChek™ Blood Glucose and β-Ketone Meter (VGM200), the VivaChek™ Ino Blood Glucose Test Strips (VGS01), the VivaChek™ Blood β-Ketone Test Strips (VKS01), blood glucose control solutions, blood β-ketone control solutions, a lancing device, lancets, a user manual, package inserts, quick reference guide warranty card, and carrying case. The device is packaged as a single system (with all components described above), as well as packaged so that subsets of the system components may be purchased separately.

The previously cleared VivaChek™ Ino Plus blood glucose meter (k173140) has been modified to add a ketone measurement function in this submission.

B Principle of Operation:

The VivaChek™ Blood Glucose and β-Ketone Monitoring System is a quantitative assay for the detection of glucose and/or β-ketone 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 and the resulting β-ketone value is displayed on the meter.

V Substantial Equivalence Information:

A Predicate Device Name(s):
KetoSens Blood B-Ketone Monitoring System

B Predicate 510(k) Number(s):
K170463

C Comparison with Predicate(s):

Device & Predicate Device(s):	K192957	K170463
Device Trade Name	VivaChek™ Blood Glucose and β-Ketone Monitoring System (Model: VGM200)	KetoSens Blood β-Ketone Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the quantitative measurement of β-	Same

Device & Predicate Device(s):	K192957	K170463
	Ketone in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control program.	
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
General Device Characteristic Differences		
Operating Temperature	41 – 113 °F	50 – 100 °F
Sample Volume	0.8 µL	0.5 µL
Hematocrit Range	20–70%	20–55%

VI Standards/Guidance Documents Referenced:

CLSI EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline.

CLSI EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.

CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline.

CLSI EP25-A Evaluation of Stability of In Vitro diagnostic reagents; Approved Guideline.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Repeatability was assessed using venous whole blood samples adjusted by spiking with D-3-hydroxybutyrate. Each blood ketone concentration was tested in replicates using the

candidate device and with the Randox RANBUT D-3-Hydroxybutyrate assay run on the Randox RX Imola chemistry analyzer, as the comparator method to verify the concentrations. Ten replicates were tested per meter per concentration with each of the three lots of the test strips. The results are summarized below:

Concentration (mmol/L)	N	Mean	SD	%CV
0.1-0.6	300	0.32	0.04	11.4%
0.9-1.5	300	1.30	0.06	4.7%
2.0-3.0	300	2.34	0.09	3.8%
4.0-5.0	300	4.37	0.16	3.6%
6.0-8.0	300	6.76	0.24	3.6%

Intermediate Precision study:

Intermediate precision was evaluated using three lots of the blood ketone test strips with 10 meters. Three levels of control solutions were used. For each control, ten replicates were taken each day for ten days, so that 100 individual measurements were generated per control level. The results from all strip lots are summarized below:

Sample	N	Mean	SD	%CV
Level 1	300	0.61	0.04	6.5%
Level 2	300	2.23	0.08	3.5%
Level 3	300	4.48	0.17	3.8%

2. Linearity:

The linearity of the Ketone Monitoring System was evaluated using venous whole blood spiked with β-hydroxybutyrate. Twelve whole blood samples were adjusted to the following β-hydroxybutyrate concentrations: 0.07, 0.25, 0.53, 1.04, 1.79, 2.32, 3.15, 4.14, 5.02, 6.33, 7.37, and 8.52 mmol/L. Each blood ketone concentration was tested on the candidate device, as well as with Randox RANBUT D-3-Hydroxybutyrate assay on the Randox RX Imola chemistry analyzer as a comparator method to determine expected concentration. The summary of the of the linear regression analysis for each lot was as follow:

Test Strip Lot	Slope	y-intercept	R^2 values
Lot 1	1.01	0.06	0.9989
Lot 2	1.00	0.00	0.9987
Lot 3	0.99	0.02	0.9988

The results of the study support the sponsor's claimed (β-ketone) measuring range of 0.1-8.0 mmol/L.

Validation testing was performed demonstrating that the meter displays 'HI" when the measurement result is greater than 8.0 mmol/L and "LOW" when the measurement result is less than 0.1 mmol/L, as intended.

3. Analytical Specificity/Interference:

To evaluate interference of exogenous and endogenous interfering substances, three venous whole blood samples with ketone concentrations of 0.4 mmol/L, 1.2 mmol/L and 4.5 mmol/L were divided into two aliquots: control (with no added potential interferent) and test (with assessed potential interferent). Each sample was tested using 10 meters and the difference between meter results obtained with the test sample compared to the control samples calculated. The sponsor defined no significant interference as bias within 0.225 mmol/L for β-ketone < 1.5 mmol/L and ≤ 15% for β-ketone ≥1.5 mmol/L. The following table lists the highest tested concentration of each substance at which no significant interference was detected:

Substance	Highest concentration at which no significant interference is observed (mg/dL)
Acetaminophen	20
Acetone	60
Acetoacetate	20
Ascorbic acid	3
Acetylsalicylc Acid	45
Amoxcillin	12
Ampillicin	3
Bilirubin	20
Bicarbonate	120
Caffeine	9
Captopril	10
Cholesterol	600
Cholic Acid	6
Clonidine	1.2
Creatinine	30
D-(-)-Fructose	900
D-mannitol	1000
Dopamine	13
EDTA	200
Erythromycin	20
Estrone	0.1
Famotidine	0.15
Fluoxetine HCl	0.8
Galactose	100
Gentisic Acid	50
Glucose	600
Hemoglobin	500
Heparin, U/dL	8000
Ibuprofen	40
Lactitol	1000
Lactose	1000

Substance	Highest concentration at which no significant interference is observed (mg/dL)
Levo-DOPA	5
Maltose	1000
Mannitol	1000
Metformin HCl	60
Methyl-Dopa	10
Metoprolol	0.27
Reduced Glutathione	20
Salicylate	60
Sorbitol	1000
Tetracycline	30
Theophylline	37.5
Tolazimide	100
Tolbutamide	100
Triglycerides	3000
Uric acid	24
Vitamin E	15
Xylitol	1000
Xylose	1000

The labeling includes the following limitations:

- Do not use this system if you are taking vitamin C (ascorbic acid in your blood > 3 mg/dL) since it could cause your glucose and ketone results to be incorrect.
- The system should not be used following xylose absorption procedures.

4. Assay Reportable Range:

   0.1 - 8.0 mmol/L

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

   Traceability:
   The VivaChek™ Blood Ketone Monitoring system is traceable to an in-house standard prepared from commercially available control materials. The method comparison / lay user study was performed using the Randox RANBUT D-3-Hydroxybutyrate assay on the RX Imola chemistry analyzer (see Section VII.C.3).

   Test strip stability:
   The Ketone Test Strips are provided in vials. The shelf life stability was assessed with real-time testing. The study protocol and acceptance criteria were reviewed and found acceptable to support the sponsor's claimed stability of 18 months when stored under recommended storage conditions of 39°F – 86°F (4-30°C) and relative humidity of 10-85%.

6. Detection Limit:

   Please refer to the linearity study above.

7. Assay Cut-Off:

   Not Applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   See section VII.3.C below for accuracy in the hands of the intended user.

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

   Lay-user accuracy study:

   To assess the performance of the VivaChek™ Blood Glucose and β-Ketone Monitoring System in the hands of the intended users, a lay user study was conducted with 102 lay user participants using three lots of ketone test strips. Each lay user participant self-tested their own fingertip capillary blood using the VivaChek™ Blood β-Ketone Monitoring System unassisted and was instructed to use instructions provided in the labeling written in English.

   The lay user β-ketone measurements were compared to those obtained with the Randox RANBUT D-3-Hydroxybutyrate assay on the RX Imola chemistry analyzer. The range of β-ketone concentrations across all subjects was 0.11 to 1.52 mmol/L. Each sample was measured in singlicate. The results are summarized below:

   Results for samples with β-ketone concentration <1.5 mmol/L:

Within ± 0.10 mmol/L	Within ± 0.20 mmol/L	Within ± 0.30 mmol/L
101/101 (100%)	101/101 (100%)	101/101 (100%)

Results for samples with β-ketone concentration ≥1.5 mmol/L

Within ± 5%	Within ± 10%	Within ± 20%
1/1 (100%)	1/1 (100%)	1/1 (100%)

Linear regression analysis of the results:

Slope	Intercept	R2	N	Ketone Concentration (mmol/L)
1.0037	-0.0083	0.9927	102	0.11 to 1.52 mmol/L

Usability: At the end of the study, each participant was asked to complete a usability questionnaire regarding ease of understanding of information in the user manual and the ease of use when performing a blood glucose test. From the sponsor's analysis of the questionnaire responses, the participants overall were satisfied with the ease of operation by following the instructions for use in the User's Manual and the overall performance of the VivaChek™ Blood Glucose and β-Ketone Monitoring System.

Readability: The readability of the over-the counter, home use labeling was evaluated using a Flesch-Kincaid analysis and demonstrated that the grade level scores were less than 8th grade.

D Clinical Cut-Off:

Not Applicable.

E Expected Values/Reference Range:

Based on published literature, the sponsor included the following in the labeling:

The normal adult blood β-Ketone range for a person without diabetes is less than 0.6 mmol/L.

A. Rewers, Current Controversies in Treatment and Prevention of Diabetic Ketoacidosis, Advances in Pediatrics 57 (2010) 247–267.

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.