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

I Background Information:

A 510(k) Number

K233058

B Applicant

VivaChek Biotech (Hangzhou) Co., Ltd.

C Proprietary and Established Names

VivaChek™ Link Plus Blood Glucose 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

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Glucose in capillary whole blood from the fingertip

C Type of Test:

Quantitative amperometry (glucose oxidase).

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

VivaChek™ Link Plus Blood Glucose Monitoring System is comprised of VivaChek™ Link Plus Blood Glucose Meter and the VivaChek™ Ino Blood Glucose Test Strips. VivaChek™ Link 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.

C Special Conditions for Use Statement(s):
OTC - Over The Counter

- Not for use on critically ill patients, patients in shock or in a hyperglycemic-hyperosmolar state with or without ketosis.
- Not for neonatal use.
- Not for use on patient with severe dehydration.
- Not for use on patient that is severely hypotensive.
- Not for screening 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 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 meter 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™ Link Plus Blood Glucose Meter

IV Device/System Characteristics:

A Device Description:

VivaChek™ Link Plus Blood Glucose Monitoring System, is designed to quantitatively measure the glucose concentration in fresh capillary whole blood from the fingertip. The system consists of: VivaChek™ Link Plus Blood Glucose Meter, VivaChek™ Ino Blood Glucose Test Strips, and the VivaChek™ Ino Control Solution with three levels (level 1, 2 and 3). The blood glucose meter contains a 3.7-volt lithium Ion Battery that can be charged using USB port, plastic housing and Buttons and a 4G module for data transmission. The materials needed but not provided include a single user lancing device (VivaChek lancing device) and sterile lancets (VivaChek lancets) both cleared under K220475, VivaChek™ Ino Control Solution and VivaChek™ Ino Blood Glucose Test Strips.

B Principle of Operation:

VivaChek™ Link Plus Blood Glucose Monitoring System 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 oxidase and the mediator. Electrons are generated, producing a current that is proportional to the glucose concentration in the sample. After the reaction time, the glucose concentration in the sample is displayed.

C Instrument Description Information:

1. Instrument Name:

   VivaChek™ Link Plus Blood Glucose 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:

   The glucose system is intended to be used with capillary whole blood from the finger only. The whole blood sample is applied directly to the test strip by capillary action.

4. Calibration:

   The meter does not require calibration or coding by the user. The meter is automatically coded.

5. Quality Control:

   Three levels of glucose control solutions are available for use with this system and can be purchased separately. Recommendations on when to test with control solutions are provided in the labeling. Acceptable ranges for each level of control solution are printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges. The control solution readings are automatically marked by the meter as control results and are not included in the patient result averages.

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

V Substantial Equivalence Information:

A Predicate Device Name(s):

VivaChek™ Ino Smart Blood Glucose Monitoring System

B Predicate 510(k) Number(s):

K173140

C Comparison with Predicate(s):

Device & Predicate Device(s):	K233058	K173140
Device Trade Name	VivaChek™ Link Plus Blood Glucose Monitoring System	VivaChek Ino Smart Blood Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the 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.	Same
Test Strip	VivaChek™ Ino Blood Glucose Test Strips	Same
Strip Chemical Composition	Glucose oxidase	Same
Sample Type	Fresh capillary whole blood	Same
Measurement Range	20-600 mg/dL	Same
Sample Volume	0.8 µL	Same
Test Time	5 seconds	Same
General Device Characteristic Differences		
Battery Type	Rechargeable, 800 mAh, 3.7 Volt DC, lithium polymer battery	Rechargeable, 250mAh, 3.7 Volt DC, lithium polymer battery
Data Transmission	4G	Bluetooth

VI Standards/Guidance Documents Referenced:

FDA Guidance Document: Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use. Guidance for Industry and Food and Drug Administration Staff. Issued on September 29, 2020.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Within-Run Precision (Repeatability)

The sponsor performed a repeatability study using 3 lots of VivaChek™ Ino Blood Glucose Test Strips, 10 VivaChek™ Link Plus Blood Glucose Meters and venous whole blood adjusted to 5 glucose concentration levels (i.e., Level 1: 30 to 50 mg/dL, Level 2: 51 to 110 mg/dL, Level 3: 111 to 150 mg/dL, Level 4: 151 to 250 mg/dL, and Level 5: 251 to 400 mg/dL). Each sample was tested in replicates of 10 on each of 10 meters using 3 lots of test strips for a total of 300 tests per glucose concentration. Results are summarized below:

Glucose Level (mg/dL)	Strip Lot	n	Mean (mg/dL)	SD (mg/dL)	%CV
Level 1 (30 to 50)	1	100	40.0	1.7	4.3%
	2	100	40.2	1.8	4.4%
	3	100	40.3	1.7	4.3%
	Combined	300	40.2	1.7	4.3%
Level 2 (51 to 110)	1	100	70.5	2.1	2.9%
	2	100	70.4	2.2	3.1%
	3	100	70.5	2.0	2.9%
	Combined	300	70.4	2.1	3.0%
Level 3 (111 to 150)	1	100	129.4	4.0	3.1%
	2	100	129.2	3.6	2.8%
	3	100	129.7	3.4	2.6%
	Combined	300	129.4	3.6	2.8%
Level 4 (151 to 250)	1	100	200.2	4.9	2.4%
	2	100	200.3	5.1	2.5%
	3	100	198.4	5.8	2.9%
	Combined	300	199.6	5.3	2.7%
Level 5 (251 to 400)	1	100	349.3	8.7	2.5%
	2	100	351.7	9.1	2.6%
	3	100	349.8	7.8	2.2%
	Combined	300	350.3	8.6	2.5%

Intermediate Precision (Between Run)

Intermediate precision study was performed using 3 lots of VivaChek™ Ino Blood Glucose Test Strips, 10 VivaChek™ Link Plus Blood Glucose Meters, and 5 levels of glucose control solutions (i.e., Level 1: 30 to 50 mg/dL, Level 2: 51 to 110 mg/dL, Level 3: 111 to 150 mg/dL, Level 4: 151 to 250 mg/dL, and Level 5: 251 to 400 mg/dL). Each sample level was measured once a day with each meter and each test strip lot for 10 days, for a total of 300 replicates per level. Results are summarized below:

Glucose Level (mg/dL)	Strip Lot	n	Mean (mg/dL)	SD (mg/dL)	%CV
Level 1 (30 to 50)	1	100	40.0	1.5	3.7%
	2	100	39.9	1.4	3.6%
	3	100	40.3	1.4	3.6%
	Combined	300	40.0	1.5	3.7%
Level 2 (51 to 110)	1	100	69.8	1.8	2.6%
	2	100	70.4	1.7	2.4%
	3	100	69.8	1.8	2.6%
	Combined	300	70.1	1.8	2.6%
Level 3 (111 to 150)	1	100	130.1	3.2	2.5%
	2	100	129.7	3.3	2.6%
	3	100	130.4	3.1	2.4%
	Combined	300	130.1	3.2	2.5%
Level 4 (151 to 250)	1	100	199.1	5.1	2.5%
	2	100	200.1	4.8	2.4%
	3	100	198.9	4.9	2.4%
	Combined	300	199.5	4.9	2.5%
Level 5 (251 to 400)	1	100	349.3	8.5	2.4%
	2	100	350.2	8.7	2.5%
	3	100	349.6	6.6	2.4%
	Combined	300	349.9	8.6	2.4%

2. Linearity:

A linearity study was conducted with 2 VivaChek™ Link Plus Blood Glucose Meters, 3 lots of VivaChek™ Ino Blood Glucose Test Strips, and 11 blood glucose concentration levels (19, 76, 135, 195, 250, 310, 365, 428, 482, 540, and 600 mg/dL) as determined by the comparative method (YSI 2300 STAT PLUS Glucose and L-Lactate Analyzer). VivaChek™ Link Plus Blood Glucose Monitoring System results were compared with the values obtained from the comparative method. The results from the linear regression analysis are summarized below:

Test Strip Lot#	**Slope**	**y-intercept**	**R^2-value**
Lot 1	0.9968	0.9922	0.9981
Lot 2	1.0006	1.5950	0.9980
Lot 3	0.9908	2.3351	0.9977

Combined	0.9961	1.6407	0.9979

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

3. Analytical Specificity/Interference:

Interference studies were performed with 10 VivaChek™ Link Plus Blood Glucose Meters and 3 lots of VivaChek™ Ino Blood Glucose Test Strips. The study was conducted using venous whole blood samples adjusted to 3 glucose levels (50-70, 110-130, and 225-270 mg/dL) as measured by the comparative method (YSI 2300 STAT PLUS Glucose and L-Lactate Analyzer). The adjusted blood glucose concentrations were separated into a control sample with no interferent added and a test sample containing one of 32 potentially interfering substances. No significant interference between the test and the control samples was defined by the sponsor as within ± 4.8 mg/dL at < 75 mg/dL glucose and within ± 8% at > 75 mg/dL glucose. The highest concentrations at which no significant interference t was observed are presented in the table below:

Test Substance	**Maximum tested concentration with no significant interference**
Acetaminophen	20 mg/dL
Ascorbic acid	6 mg/dL
Conjugated Bilirubin	50 mg/dL
Unconjugated Bilirubin	40 mg/dL
Cholesterol	500 mg/dL
Creatinine	15 mg/dL
Dopamine	20 mg/dL
EDTA	200 mg/dL
Galactose	60 mg/dL
Gentisic acid	27.8 mg/dL
Reduced Glutathione	92.9 mg/dL
Hemoglobin	20000 mg/dL
Heparin	800 IU/dL
Ibuprofen	50 mg/dL
L-Dopa	3 mg/dL
Maltose	480 mg/dL
Mannitol	1800 mg/dL
Methyldopa	10.5 mg/dL
Salicylic acid	60 mg/dL
Sodium	180 mmol/L
Tolbutamide	100 mg/dL
Tolazamide	40 mg/dL
Triglycerides	3000 mg/dL
Uric acid	24 mg/dL

Test Substance	Maximum tested concentration with no significant interference
Xylose	200 mg/dL
Sorbitol	0.09 mg/dL
Lactose	25 mg/dL
Tetracyline	1.5 mg/dL
Xylitol	0.09 mg/dL
Lactitol	0.09 mg/dL
Isomalt	0.09 mg/dL
Maltitol	0.09 mg/dL

The sponsor included the following statement in the labeling:

- Do not test your blood during or soon after a xylose absorption test. Xylose in the blood can give inaccurate results with this meter.

4. Assay Reportable Range:

   20 to 600 mg/dL glucose

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

   The system is traceable to NIST SRM 917c glucose reference material. A method comparison study was performed using the candidate devices and YSI 2300 STAT PLUS Glucose and L-Lactate Analyzer as the comparative method (see section VII.C.3).

   Open-vial and closed-vial Stability:
   Test strip stability was assessed with accelerated studies and real-time stability studies. Protocols and acceptance criteria were reviewed and found acceptable. The labeling includes claims that the test strips are stable for 6 months after opening and 24 months unopened when stored between of 36 to 86ºF (2 to 30ºC) and 10 to 90 % relative humidity.

6. Detection Limit:

   Please see linearity in Section VII.A.2

7. Assay Cut-Off:

   Not applicable.

8. Accuracy (Instrument):

   Not applicable.

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Please refer to lay user study below in section VII.C3.

2. Matrix Comparison:

   Not applicable.

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):

   Method Comparison/Lay User Performance Study:
   To assess the performance of the VivaChek™ Link Plus blood glucose monitoring system in the hands of lay users, the sponsor performed a study with 352 lay user participants who collected and tested their own fingertip capillary blood samples using only the instructions from the product labeling in English. The glucose concentrations in the samples ranged from 48.1 to 314.5 mg/dL, including 54 samples with glucose levels <80 mg/dL and 66 samples with glucose level >250 mg/dL, as measured by the comparator method (YSI 2300 analyzer). Results were analyzed by comparing blood glucose results obtained from the VivaChek™ Link Plus blood glucose meter by the lay user against the laboratory comparator value obtained by healthcare professionals. Results are summarized in the tables below:

VivaChek™ Link Plus Blood Glucose Monitoring System are summarized below: Accuracy Across the Entire Glucose Range:			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
243/352 (69.0 %)	339/352 (96.3 %)	352/352 (100 %)	352/352 (100 %)

Regression Analysis:
$y = 0.9965x + 0.3553$; $R^2 = 0.9942$

   Usability:

   At the end of the lay-user 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. The sponsor's analysis of the questionnaire responses demonstrated that the participants were satisfied with the ease of operation by following the instructions for use in the User's Manual and with the overall performance of the VivaChek™ Link Plus blood glucose monitoring system.

Labeling Readability:

The readability of the user manual and test strip package insert, were evaluated using a Flesch-Kincaid analysis and demonstrated that the readability was less than an 8th grade level.

Accuracy at Extreme Glucose Study:

An accuracy study was performed to evaluate the performance of VivaChek™ Link Plus Blood Glucose Monitoring System was evaluated with the 105 fingertip blood samples containing extreme glucose concentrations at the extreme lower and upper ends of the claimed glucose measuring range. Of the 105 blood samples, 53 samples were less than or equal to 80 mg/dL and 52 samples were greater than or equal to 250 mg/dL. Results on the candidate devices using 3 test strip lots were compared to the results obtained using the comparative method (YSI 2300 STAT PLUS Glucose and L-Lactate Analyzer) and are summarized below:

For glucose concentrations < 80 mg/dL:			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
29/53 (54.7 %)	49/53 (92.5%)	53/53 (100 %)	53/53 (100 %)

For glucose concentrations > 250 mg/dL:			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
33/52 (63.5 %)	48/52 (92.3 %)	52/52 (100 %)	52/52 (100 %)

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The sponsor includes the following expected blood glucose values for people without diabetes in the labeling:

Time	**Normal plasma glucose range for adults without diabetes, mg/dL**
Before breakfast (fasting)	< 100
2 hours after a meal	<140

Reference: American Diabetes Association; Standards of Medical Care in Diabetes—2023 Abridged for Primary Care Providers. Clin Diabetes 2 January 2023; 41 (1): 4–31.

F Other Supportive Instrument Performance Characteristics Data:

1. Hematocrit Study
   The effect of hematocrit on the VivaChek™ Link Plus Blood Glucose Monitoring System was evaluated with venous blood samples adjusted to hematocrit levels of 20%, 25%, 30%, 35%, 42%, 50%, 55%, 60%, 65%, and 70%. Each hematocrit level was adjusted to achieve five concentrations of glucose (30 to 50, 51 to 110, 111 to 150, 151 to 250, and 251 to 400 mg/dL). Each blood sample was tested using 10 VivaChek™ Link Plus Blood Glucose Meters with 3 lots of VivaChek™ Ino Blood Glucose Test Strips and tested on the YSI 2300 comparator method. The glucose values were compared to results obtained on the YSI 2300 comparator method, and to the normal hematocrit sample. The results support the claimed hematocrit range of 20% to 70% for the VivaChek™ Link Plus Blood Glucose Monitoring System.

2. System Operating Conditions Study
   The sponsor performed an operating condition study using venous whole blood samples adjusted to 3 glucose levels (60 to 70, 100 to 120, and 300 to 400 mg/dL). Testing was conducted under the following five temperature and relative humidity (RH) combinations: 113°F (45°C) and 41°F (5°C), at 10% and 90% RH each and at 73°F (23°C) at 40% RH. The candidate system results were compared to results from the YSI 2300 comparator method. The results support the claims in the labeling that the system can be used in conditions of 41–113°F (5-45°C) with relative humidity of 10 to 90%.

3. Altitude Effects
   The effect of altitude on the VivaChek™ Link Plus Blood Glucose Monitoring System was evaluated by testing whole blood samples at sea level (130 ft) and at 10,413 ft above sea level. The candidate system results were compared to those obtained with the comparator method (YSI 2300 analyzer). The results support the claims that the system functions as intended at altitudes up to the claimed altitude of 10,413 feet.

4. Sample Volume Study
   The sponsor conducted a sample volume study using venous blood samples prepared at three glucose range intervals at thee glucose levels (50-65, 110-120, and 200-250 mg/dL) that were tested at different sample volumes (0.6, 0.7, and 0.8 µL). The candidate system results were compared against the YSI 2300 comparator method measurements. Results support the claimed minimum sample volume of 0.8 µL. The sponsor also provided validation studies demonstrating that with blood volumes below 0.8 µL, the insufficient sample volume error message functioned as intended.

5. Flex Studies
   Intermittent sampling, sample perturbation, testing with used test strips, test strip early removal, drop/shock testing, and vibration testing was completed. The testing performed demonstrated that VivaChek™ Link Plus Blood Glucose Monitoring Systems are robust to intermittent sampling, sample perturbation, drop/shock, and vibration, and that an error message is returned to the user if a used test strip is inserted into the meter or test strip removal happens early.

6. Infection Control Studies
   The VivaChek™ Link Plus Blood Glucose Monitoring Systems is intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meters by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Clorox Germicidal Wipes, 0.55% sodium hypochlorite (EPA Registration # 67619-12). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 608 cleaning and disinfection cycles with the Clorox Germicidal Wipes. The robustness studies were designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7. Electrical Safety and EMC Studies
   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.

8. Test Strip Lot Release Protocol
   The test strip lot release protocol and acceptance 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.