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

I Background Information:

A 510(k) Number

K222126

B Applicant

Vivachek Biotech (Hangzhou) Co., Ltd

C Proprietary and Established Names

VivaChek™ Fad Blood Glucose Monitoring System,
VivaChek™ Fad Smart Blood Glucose Monitoring System,
VivaChek™ Fad Sync 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 devices

B Measurand:

Glucose in capillary whole blood from fingertip

C Type of Test:

Quantitative amperometric assay, glucose dehydrogenase (FAD-GDH)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indication(s) for Use below.

B Indication(s) for Use:

VivaChek™ Fad Blood Glucose Monitoring System is comprised of the VivaChek™ Fad Blood Glucose Meter and the VivaChek™ Fad Blood Glucose Test Strips. VivaChek™ Fad 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™ Fad Smart Blood Glucose Monitoring System is comprised of the VivaChek™ Fad Smart Blood Glucose Meter and the VivaChek™ Fad Blood Glucose Test Strips. VivaChek™ Fad 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™ Fad Sync Blood Glucose Monitoring System is comprised of the VivaChek™ Fad Sync Blood Glucose Meter and the VivaChek™ Fad Blood Glucose Test Strips. VivaChek™ Fad 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 tomonitor 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

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients.
- Not for use on critically ill patients, patients in shock or in a hyperglycemic-hyperosmolar state with or without ketosis.
- Not for use on patients with severe dehydration.
- Not for use on patients that are severely hypotensive.
- Not for neonatal use.
- Not for Alternative Site Testing (AST).
- Not for screening or diagnosis of diabetes mellitus.

- Do not use at altitudes above 10413ft (3174 meters) above sea level.
- 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™ Fad Blood Glucose Meter
VivaChek™ Fad Smart Blood Glucose Meter
VivaChek™ Fad Sync Blood Glucose Meter

IV Device/System Characteristics:

A Device Description:

The VivaChek™ Fad Blood Glucose Monitoring System, the VivaChek™ Fad Smart Blood Glucose Monitoring System, and the VivaChek™ Fad Sync Blood Glucose Monitoring System share the same device technology and the same intended use. Each of the device systems is comprised of a VivaChek™ Fad Blood Glucose Meter (Fad, Fad Smart, or Fad Sync, respectively) and VivaChek™ Fad Blood Glucose Test Strips (sold separately). The device systems differ in minor design features and certain user functions. The VivaChek™ Fad Blood Glucose Monitoring System contains a user-replaceable single 3.0V CR 2032 coin battery and a strip ejector button. The VivaChek ™ Fad Smart and VivaChek ™ Fad Sync Blood Glucose Monitoring Systems contain a non-serviceable rechargeable 3.7 Volt lithium ion battery, a micro USB port for recharging, and have minor differences in exterior meter materials and color.

The following items are compatible with the device systems but are not included with the purchase of the meter and are available for purchase separately:

- VivaChek™ Fad Control Solutions (Level 1, Level 2, and Level 3)
- VivaChek™ Lancing Device and VivaChek™ Lancets (k220475).

B Principle of Operation:

The VivaChek™ Fad, VivaChek™ Fad Smart and VivaChek™ Fad Sync Blood Glucose Monitoring Systems are designed to quantitatively measure the glucose concentration in fresh capillary whole blood. The blood sample is pulled into the tip of the test strip through capillary action. The glucose measurement is based amperometry achieved through the electrical current caused by the reaction of the glucose with glucose dehydrogenase and a mediator of the test strip, producing a current that positively correlates to the glucose concentration in the blood sample. The system is calibrated to display plasma equivalent results. After the reaction time, the glucose concentration in the sample is displayed on the meter.

C Instrument Description Information

1. Instrument Name:

   VivaChek™ Fad Blood Glucose Meter
   VivaChek™ Fad Smart Blood Glucose Meter
   VivaChek™ Fad Sync 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:

   Samples are to be tested immediately upon collection.

4. Calibration:

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

5. Quality Control:

   VivaChek™ Fad Control Solutions (Level 1, Level 2, and Level 3) are available for use with the system. Each test strip vial is printed with a control solution range, and the user is instructed to compare the control results with the expected control ranges printed on the strip vial. 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 control solutions are automatically recognized by the meter and the results marked as control results and are not included in the patient result averages.

V Substantial Equivalence Information:

A Predicate Device Name(s):

TD-4183 Blood Glucose Monitoring System

B Predicate 510(k) Number(s):

K190579

C Comparison with Predicate(s):

Device & Predicate Device(s):	K222126	K222126	K222126	K190579
Device Trade Name	VivaChek™ Fad Blood Glucose Monitoring System	VivaChek™ Fad Smart Blood Glucose Monitoring System	VivaChek™ Fad Sync Blood Glucose Monitoring System	TD-4183 Blood Glucose Monitoring System
General Device Characteristic Similarities				
Intended Use/Indications For Use	For the quantitative measurement of 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	Same	Same
General Device Characteristic Differences				
Battery	CR 2032 3.0 V	Rechargeable 3.7 V lithium ion	Rechargeable 3.7 V lithium ion	1.5V AAA

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" (September 29, 2020)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

Unless otherwise noted, the studies detailed below were performed with the VivaChek™ Fad Blood Glucose Monitoring System. The differences between the three meters in this submission

(VivaChek™ Fad, VivaChek™ Fad Smart and VivaChek™ Fad Sync) are minor design features, as described above in section IV. Therefore, the studies for the VivaChek™ Fad meter are representative of the performance of all device systems in this 510(k) submission.

1. Precision/Reproducibility:

Repeatability precision (within-run precision):
Within-run precision studies were performed using venous whole blood samples 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 10 times on each of 10 VivaChek™ Fad meters using 3 lots of VivaChek™ Fad Blood Glucose 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	38.9	1.6	4.0%
	2	100	39.3	1.5	3.9%
	3	100	38.7	1.7	4.5%
	Pooled	300	39.0	1.6	4.2%
Level 2 (51 to 110)	1	100	67.1	2.5	3.7%
	2	100	70.4	2.2	3.1%
	3	100	68.5	2.2	3.3%
	Pooled	300	68.7	2.7	3.9%
Level 3 (111 to 150)	1	100	127.0	3.3	2.6%
	2	100	124.6	3.1	2.5%
	3	100	127.1	3.5	2.8%
	Pooled	300	126.2	3.5	2.8%
Level 4 (151 to 250)	1	100	198.0	4.5	2.2%
	2	100	198.5	4.6	2.3%
	3	100	197.5	4.6	2.3%
	Pooled	300	198.0	4.6	2.3%
Level 5 (251 to 400)	1	100	321.3	8.8	2.7%
	2	100	319.1	8.6	2.7%
	3	100	326.0	9.9	3.0%
	Pooled	300	323.0	8.1	2.5%

Intermediate Precision:
Intermediate precision of the glucose measurement was evaluated using 3 lots of VivaChek™ Fad Blood Glucose Test Strips, 10 VivaChek™ Fad 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	40.7	1.2	2.8%
	2	100	40.7	1.2	2.9%
	3	100	40.8	1.2	3.0%
	Pooled	300	40.7	1.2	2.9%
Level 2 (51 to 110)	1	100	70.0	2.1	3.0%
	2	100	70.3	1.9	2.7%
	3	100	70.0	2.1	3.0%
	Pooled	300	70.1	2.0	2.9%
Level 3 (111 to 150)	1	100	129.4	2.7	2.1%
	2	100	130.3	2.7	2.0%
	3	100	130.0	2.6	2.0%
	Pooled	300	129.8	2.7	2.1%
Level 4 (151 to 250)	1	100	199.1	4.0	2.0%
	2	100	199.3	4.1	2.1%
	3	100	199.0	3.9	2.0%
	Pooled	300	199.2	4.0	2.0%
Level 5 (251 to 400)	1	100	349.9	7.5	2.2%
	2	100	350.1	7.0	2.0%
	3	100	350.4	7.5	2.1%
	Pooled	300	349.9	7.3	2.1%

2. Linearity:

A linearity study was conducted with 11 venous whole blood glucose concentration levels (20, 78, 136, 194, 252, 310, 368, 426, 484, 542, and 600 mg/dL) as determined by the comparative method (YSI 2300 STAT PLUS Glucose and L-Lactate Analyzer). The results from the VivaChek™ Fad meter were compared with the values obtained from the comparator method. The results from the regression analysis are summarized below:

Test Strip Lot #	Slope	y-intercept	R^2-value
Lot 1	0.9902	0.9574	0.9985
Lot 2	0.9954	0.4356	0.9989
Lot 3	0.9986	0.2892	0.9988
Combined	0.9947	0.5607	0.9987

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 to evaluate the effect of endogenous substances and common exogenous substances expected in the intended use population. The study was conducted using venous whole blood samples adjusted to 3 glucose levels (60, 120, and 250 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. The VivaChek™ Fad meter measurements were averaged and the bias between the test samples and the control samples was calculated. The highest concentrations at which no significant interference (defined by the sponsor as bias vs. control being greater than ± 4.8 mg/dL at < 75 mg/dL and ± 8 % at > 75 mg/dL) effect was observed are presented in the table below:

Substance	Highest 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	20 g/dL
Heparin	8000 IU/L
Ibuprofen	50 mg/dL
L-Dopa (Levo- 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	1500 mg/dL
Uric Acid	24 mg/dL
Xylose	6.25 mg/dL
Sorbitol	0.09mg/dL
Lactose	25 mg/dL

Substance	Highest Concentration with No Significant Interference
Tetracycline	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 statements in the labeling:

- Do not test your blood glucose 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):

   Traceability
   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).

   Test Strip Stability Testing
   Open-vial and closed-vial test strip stability was assessed with accelerated and real-time 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:

   The reportable range for the device systems is 20 to 600 mg/dL.

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 performance 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 in the hands of the intended users, the sponsor performed two independent lay user performance studies with either the VivaChek™ Fad Blood Glucose Monitoring System or the VivaChek™ Fad Smart Blood Glucose Monitoring System. The VivaChek™ Fad Sync Blood Glucose Meter is similar in form and function to the VivaChek™ Fad Smart Blood Glucose Meter (as described above in section IV). Therefore, the lay user performance study for the VivaChek™ Fad Smart meter is applicable to the VivaChek™ Fad Sync meter.

   The performance of the VivaChek™ Fad Blood Glucose Monitoring System was evaluated in the hands of 567 intended users at 3 study sites. The performance of the VivaChek™ Fad Smart Blood Glucose Monitoring System was evaluated in the hands of 353 intended users at 3 study sites. The participants in both studies were provided with the device labeling in English, collected their own fingertip capillary sample, and performed a blood glucose measurement without additional training. The blood glucose results obtained by lay users were compared against the results obtained with a laboratory-based comparative method (YSI 2300 STAT PLUS Glucose and L-Lactate Analyzer).

   Results for the VivaChek™ Fad Blood Glucose Monitoring System are summarized below:

System Accuracy Results for Glucose Range			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
317/567 (55.9 %)	490/567 (86.4 %)	558/567 (98.4 %)	567/567 (100 %)

Regression Analysis		
Slope	y-intercept	R^2-value
0.9838	1.4030	0.9837

Results for the VivaChek™ Fad Smart Blood Glucose Monitoring System are summarized below:

System Accuracy Results for Glucose Range			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
197/353 (55.8 %)	304/353 (86.1 %)	348/353 (98.6 %)	353/353 (100 %)

Regression Analysis		
Slope	y-intercept	R^2-value
0.9966	- 0.3409	0.9808

Usability

At the end of the lay-user studies, 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 were satisfied with the ease of operation following the instructions for use in the labeling and with their overall ability to conduct testing with the candidate device.

Readability

The results Flesch-Kincaid readability assessment demonstrated that the User Manual and the test strip package insert were written at an 8th grade level or less.

Accuracy at Extreme Glucose Study

An accuracy study was performed to evaluate the performance of the VivaChek™ Fad and Fad Smart Blood Glucose Monitoring Systems with 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, 29 samples were altered with glycolysis to obtain glucose concentrations ≤ 80 mg/dL and 18 samples were supplemented with additional glucose to obtain glucose concentrations ≥ 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:

Results for the VivaChek™ Fad Blood Glucose Monitoring System are summarized below:

Glucose Levels	Accuracy Results for Extreme Glucose Study			
	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Extreme Low (<80mg/dL)	39/53 (73.6 %)	51/53 (96.2 %)	53/53 (100 %)	53/53 (100 %)
Extreme High (>250mg/dL)	31/52 (59.6 %)	44/52 (84.6 %)	52/52 (100 %)	52/52 (100 %)

Results for the VivaChek™ Fad Smart Blood Glucose Monitoring System are summarized below:

Glucose Levels	Accuracy Results for Extreme Glucose Study			
	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Extreme Low (<80mg/dL)	40/53 (75.5 %)	52/53 (98.1 %)	53/53 (100 %)	53/53 (100 %)
Extreme High (>250mg/dL)	32/52 (61.5 %)	43/52 (82.7 %)	52/52 (100 %)	52/52 (100 %)

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The sponsor includes the following in their labeling:

Expected blood glucose values for people without diabetes:

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 was evaluated with venous blood samples adjusted to hematocrit levels of 20 to 70 % (20, 25, 30, 35, 42, 50, 55, 60, 65, and 70 %) at five glucose levels (30 to

50, 51 to 110, 111 to 150, 151 to 250, and 251 to 400 mg/dL). The results obtained with the device system were compared to those obtained with the comparator method (YSI 2300 analyzer). The results demonstrated acceptable performance of the candidate blood glucose monitoring systems across the claimed hematocrit range of 20 to 70%.

2. Altitude Study
   To evaluate the effects of altitude, a study was conducted using whole blood samples altered to achieve 15 glucose concentrations ranging from 50.2 to 540.5 mg/dL Testing was conducted at 10,413 feet. The results of obtained with the device system were compared to those obtained with the comparator method (YSI 2300 analyzer). The results support the claims that the device systems function as intended at altitudes up to the claimed altitude of 10,413 feet.

3. System Operating Conditions Study
   To evaluate device performance over varying operating temperature and humidity conditions, venous whole blood samples were adjusted to 3 glucose levels (60 to 70, 100 to 200, and 300 to 400 mg/dL). Testing was conducted under 4 combinations of temperature and relative humidity (RH) including 113°F (45°C) and 41°F (5°C) each at 10% and 90% RH, and under the nominal condition of 73°F (23°C) at 40% RH. The results obtained with the candidate systems were compared to those obtained with the comparator method (YSI 2300 analyzer). The results support the claims in the labeling that the device systems can be used in conditions of 41 to 113°F (5 to 45°C) with relative humidity of 10 to 90%.

4. Sample Volume Study
   Venous blood samples were prepared at 3 glucose range intervals (50 to 65, 100 to 120, and 200 to 250 mg/dL) and were tested at different sample volumes (0.6, 0.7, and 0.8 µL). The results obtained with the device systems were compared to those obtained with the comparator method (YSI 2300 analyzer). The results support the claimed minimum sample volume of 0.8 µL for the device systems. The sponsor provided validation studies demonstrating that with blood volumes below 0.8 µL, the insufficient sample volume error message functioned as intended.

5. Flex Studies
   The following additional flex studies were performed with the device system: drop/shock, early test strip removal, intermittent sampling, sample outside measuring range, sample perturbation, shipping, used test strips and vibration testing. The results demonstrated that the performance of the device systems is robust under these conditions.

6. Infection Control Studies
   The device systems are intended for single-patient use only. Disinfection efficacy studies were performed on the external meter materials by an outside commercial laboratory to demonstrate complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant Clorox Healthcare Bleach Germicidal Wipes (EPA Registration No. 67619-12).

   Robustness studies performed by the sponsor using each of the three device systems demonstrated that there was no change in the performance of the systems or in the external materials of the meters after 608 cycles of cleaning and disinfection using Clorox Healthcare Bleach 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 device systems were 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.