



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

I Background Information:

A 510(k) Number

K243060

B Applicant

Guangdong Transtek Medical Electronics Co., Ltd.

C Proprietary and Established Names

TeleRPM Gen2 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:

TeleRPM Gen2 Blood Glucose Monitoring System is comprised of the TeleRPM Gen2 Blood Glucose Meter and the TeleRPM Blood Glucose Test Strips. TeleRPM Gen2 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
- Single patient use only.
- 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 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:

TeleRPM Gen2 Blood Glucose Meter.

IV Device/System Characteristics:

A Device Description:

The TeleRPM Gen2 Blood Glucose Monitoring System consists of the TeleRPM Gen2 Blood Glucose Meter and the TeleRPM Blood Glucose Test Strips. The TeleRPM Blood Glucose Test Strips, TeleRPM Control Solutions (Levels 1, 2 and 3), TeleRPM Lancing Device, and TeleRPM Lancets are sold separately.

B Principle of Operation:

The TeleRPM Gen2 Blood Glucose Monitoring System is designed to quantitatively measure the glucose concentration in fresh capillary whole blood. The glucose measurement is achieved by using an amperometric detection method. The test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on 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 in the test strip generating electrons and producing a current that is proportional to the glucose concentration in the sample. After the reaction time, the glucose concentration is calculated by the meter from the detected current and the resulting glucose concentration is displayed by the meter as plasma equivalent values.

C Instrument Description Information:

1. Instrument Name:

TeleRPM Gen2 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 blood glucose monitoring 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. If the control result falls outside these ranges, the user is cautioned not to use the meter and to contact customer support. The control solution readings are automatically marked by the meter as control results and are not included in the patient result averages.

V Substantial Equivalence Information:

A Predicate Device Name(s):

VivaChek™ Link Plus Blood Glucose Monitoring System

B Predicate 510(k) Number(s):

K233058

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K243060</u>	<u>K233058</u>
Device Trade Name	TeleRPM Gen2 Blood Glucose Monitoring System	VivaChek™ Link Plus Blood Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	It is intended to quantitatively measure the glucose concentration in fresh capillary whole blood samples. It is intended for use by persons with diabetes at home as an aid to monitor the effectiveness of diabetes control.	Same
Data Transmission	4G	Same
General Device Characteristic Differences		
Battery capacity/voltage and type of battery	1300 mAh, 3.7 V, (5V input charge voltage)	800 mAh, 3.7 V, (5V input charge voltage)
Memory	2000 records	500 records

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.

IEC 60601-1-2 Edition 4.1: Medical Electrical Equipment Part 1-2: General Requirement for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Within-Run Precision (Repeatability):

Within-run precision studies were performed using venous whole blood samples adjusted to 5 glucose concentration levels (30 to 50, 51 to 110, 111 to 150, 151 to 250, 251 to 400 mg/dL). Each sample was tested in replicates of 10 with 3 lots of TeleRPM Blood Glucose Test Strips and 10 TeleRPM Gen2 Blood Glucose Meters for a total of 300 tests per glucose level. Results are summarized below:

Glucose Level (mg/dL)	Strip Lot	N	Mean (mg/dL)	SD (mg/dL)	%CV
30 to 50	1	100	40.1	1.6	4.0
	2	100	39.3	1.7	4.2
	3	100	39.8	1.6	3.9
	Combined	300	39.7	1.6	4.1
51 to 110	1	100	70.2	2.0	2.8
	2	100	70.1	1.9	2.8
	3	100	70.3	2.0	2.9
	Combined	300	70.2	2.0	2.8
111 to 150	1	100	127.8	3.6	2.8
	2	100	128.1	3.4	2.6
	3	100	128.0	2.9	2.3
	Combined	300	128.0	3.3	2.6
151 to 250	1	100	199.8	5.6	2.8
	2	100	199.4	4.9	2.5
	3	100	198.6	5.5	2.8
	Combined	300	199.2	5.4	2.7
251 to 400	1	100	321.9	7.1	2.2
	2	100	319.8	8.3	2.6
	3	100	323.2	7.8	2.4
	Combined	300	321.6	7.9	2.4

Intermediate Precision (Between Run):

Intermediate (between run) precision was evaluated using 5 levels of glucose control solutions (30 to 50, 51 to 110, 111 to 150, 151 to 250, 251 to 400 mg/dL) with 3 TeleRPM Blood Glucose Test Strip lots and 10 TeleRPM Gen2 Blood Glucose Meters. Each control solution level was measured once a day for 10 days with each meter and test strip lot, for a total of 100 replicates per control solution level per test strip lot for a total of 300 replicates for each glucose control solution level. Results are summarized below:

Glucose Level (mg/dL)	Strip Lot	N	Mean (mg/dL)	SD (mg/dL)	%CV
30 to 50	1	100	37	1.5	3.9
	2	100	36.7	1.4	3.8
	3	100	36.9	1.5	4.0
	Combined	300	36.8	1.4	3.9
51 to 110	1	100	74.2	1.9	2.5
	2	100	74.2	1.9	2.6
	3	100	74.3	2.0	2.7
	Combined	300	74.2	1.9	2.6
111 to 150	1	100	129.6	3.0	2.3
	2	100	129.8	2.9	2.2
	3	100	129.6	3.1	2.4
	Combined	300	129.6	3.0	2.3
151 to 250	1	100	209.6	5.4	2.6
	2	100	209.8	5.1	2.4
	3	100	210.9	5.2	2.5
	Combined	300	210.2	5.3	2.5
251 to 400	1	100	363.6	9.1	2.5
	2	100	363.9	8.6	2.4
	3	100	365	9.4	2.6
	Combined	300	364.2	9.0	2.5

2. Linearity:

A linearity study was conducted using venous whole blood samples adjusted to 11 glucose levels (20.1, 76.4, 135, 195.3, 248.4, 310.4, 367.2, 423, 481, 541, and 601 mg/dL as measured by the YSI 2300 STAT PLUS Glucose and L-Lactate analyzer comparator method) with 2 TeleRPM Gen2 Blood Glucose Meters and 3 lots of TeleRPM Gen2 Blood Glucose Test Strips. TeleRPM Gen2 Blood Glucose Monitoring System glucose concentration results were compared to those obtained using the comparator method. The results of the regression analysis are summarized below:

Test Strip Lot#	Slope	y-intercept	R ² -value
Lot 1	0.9979	0.9984	0.998
Lot 2	0.9951	1.3304	0.9974
Lot 3	0.9912	2.551	0.9979
Combined	0.9947	1.6266	0.9978

The results of the study support the sponsor's claimed glucose measuring range of 20 to 600 mg/dL. The meter displays "Low Result" with glucose values below 20 mg/dL and "High Result" with glucose values over 600 mg/dL. The low and high functions were validated and were demonstrated to function as intended.

3. Analytical Specificity/Interference:

Interference studies were performed with the TeleRPM Gen2 Blood Glucose Monitoring System. The study was conducted by using venous whole blood adjusted to three glucose levels (50 to 70, 110 to 130, and 225 to 270 mg/dL). 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 % bias was calculated from the difference between the test sample and the control sample using the mean of replicates for each of the 3 strip lots tested. The highest tested concentrations at which no significant interference (the mean bias for the test sample is within $\pm 10\%$ of the control mean) was observed are presented in the table below:

Test Substances	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	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
Xylose	200 mg/dL
Sorbitol	0.09mg/dL
Lactose	25 mg/dL
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 includes the following in the labeling:

- Do not test your blood glucose during or soon after a xylose absorption test. Xylose in the blood may 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 TeleRPM Gen2 Blood Glucose Monitoring System is traceable to the NIST SRM 917c glucose reference material. The method comparison/lay-user study (see section VII.C.3) was performed using a laboratory comparator method (YSI 2300 STAT PLUS Glucose and L-Lactate Analyzer).

Open-vial and closed-vial test strip stability:

TeleRPM Gen2 Blood Glucose Test Strip stability was assessed using accelerated and real-time stability studies. Protocols and acceptance criteria were reviewed and found acceptable to support the shelf-life and the 6-month open vial labeling claims when the test strips are stored between of 36 to 86°F (2 to 30°C) and 10 to 90 % relative humidity.

6. Detection Limit:

The reportable range 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 Evaluation Study:

To assess the performance of the TeleRPM Gen2 Blood Glucose Monitoring System in the hands of the intended lay users, the sponsor conducted a lay-user method comparison study with 489 lay user participants who collected and tested samples from their own fingertip using only the instructions from the product labeling in English. The data was collected using 3 TeleRPM Gen2 Blood Glucose test strip lots. Glucose concentrations in the samples ranged from approximately 48.5 to 414.5 mg/dL as measured by the comparator method, and included 54 native samples with glucose levels below 80 mg/dL and 105 native samples with glucose levels above 250 mg/dL. Results were analyzed by comparing blood glucose results obtained by the lay users with the TeleRPM Gen2 Blood Glucose Monitoring System against results obtained using a laboratory comparator method (YSI 2300 STAT PLUS Glucose and L-Lactate Analyzer). Results are summarized in the tables below:

Sample Site	System Accuracy Results for Glucose Range			
	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Fingertip	304/489 (62.2%)	465/489 (95.1%)	488/489 (99.8%)	489/489 (100.0%)

Regression Analysis:
$y = 0.9873x + 1.7901; R^2 = 0.9855$

Usability Evaluation Study:

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 TeleRPM Gen2 Blood Glucose Monitoring System.

Labeling Readability:

A Flesch-Kincaid readability assessment was conducted on the user's manual and the test strip package insert demonstrating that the readability level was less than an 8th grade reading level.

Accuracy at Extreme Glucose Study:

An accuracy study was performed to evaluate the performance of the TeleRPM Gen2 Blood Glucose Monitoring System with 141 capillary blood samples containing extreme glucose concentrations at the extreme lower and upper ends of the claimed glucose measuring range. Glucose concentrations below 80 mg/dL were achieved with 51 samples altered by glycolysis and glucose concentrations greater than 250 mg/dL were achieved with 90 samples spiked with glucose. Results on the candidate device using 3 test strip lots were compared to the results obtained using a laboratory comparator method (YSI 2300 STAT PLUS Glucose and L-Lactate Analyzer) and are summarized below:

Glucose Levels	Accuracy Results for Extreme Glucose Study			
	Within \pm 5%	Within \pm 10%	Within \pm 15%	Within \pm 20%
Extreme Low (<80mg/dL)	31/51 (60.8%)	46/51 (90.2%)	51/51 (100%)	51/51 (100%)
Extreme High (>250mg/dL)	59/90 (65.6%)	84/90 (93.3%)	90/90 (100%)	90/90 (100%)

D Clinical Cut-Off:

E Expected Values/Reference Range:

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

- < 100 mg/dL Before breakfast (fasting)
- <140 mg/dL 2 hours after a meal

Reference: American Diabetes Association; Standards of 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 different hematocrit levels on the TeleRPM Gen2 blood glucose monitoring system was evaluated using venous whole blood samples with hematocrit levels of 19 to 72 % (19, 24, 30, 36, 42, 51, 56, 61, 66, and 72%) at 5 glucose levels (40, 70, 130, 200, and 325 mg/dL). The results obtained with the candidate system were compared to

those obtained with the laboratory comparator method (YSI 2300 STAT PLUS Glucose and L-Lactate Analyzer) using the normal hematocrit (42%) samples. The results support the claimed hematocrit range of 20% to 70% for the TeleRPM Gen2 Blood Glucose Monitoring System.

2. System Operating Conditions Study:

The sponsor performed a study over varying operating temperature and humidity conditions using venous whole blood samples adjusted to 3 glucose levels (65.3, 110.5, and 347.5 mg/dL). Testing was conducted under 6 combinations of temperature and relative humidity (RH) including 114.8 °F (46 °C) and 39.2 °F (4 °C) and 8 % and 92 % RH, and under the nominal condition of 73.4 °F (23 °C) at 40 % RH. The candidate system results were compared to those obtained with the comparator method (YSI 2300 STAT PLUS Glucose and L-Lactate Analyzer) under normal condition. The results support the claims in the labeling that the TeleRPM Gen2 Blood Glucose Monitoring System can be used in conditions of 41 to 113 °F with relative humidity of 10 to 90 %.

3. Altitude Effects Study:

The effect of altitude on the TeleRPM Gen2 Blood Glucose Monitoring System was evaluated by testing 15 whole blood samples concentrations ranging from 54.7 to 504 mg/dL at sea level and at 10,413 ft above sea level. The results obtained with the candidate system were compared to those obtained with the laboratory comparator method (YSI 2300 STAT PLUS Glucose and L-Lactate Analyzer). The results support the claims that the TeleRPM Gen2 Blood Glucose Monitoring System functions as intended at altitudes up to the claimed altitude of 10,413 feet.

4. Sample Volume (Detection) Study:

The sponsor conducted a sample volume study using venous blood samples prepared at three glucose range intervals at three glucose levels (62.2, 110.5, and 225.0 mg/dL) that were tested at different sample volumes (0.6, 0.7, and 0.8 µL). The results obtained with the candidate system were compared to those obtained with the laboratory comparator method (YSI 2300 STAT PLUS Glucose and L-Lactate Analyzer). The results support the claimed sample volume of 0.8 µL and demonstrate that the insufficient sample volume error feature functions as intended with sample volumes less than 0.8 µL.

5. Flex Studies:

The following additional flex studies were performed with the candidate system: sample perturbation, testing with used test strips, test strip early removal, intermittent sampling, shock and vibration, low battery, shipping and handling simulation, meter environmental temperature and recharging temperature limit. The results demonstrated that the performance of the TeleRPM Gen2 blood glucose monitoring system is robust under these expected use conditions.

6. Infection Control Studies: The device system is intended for single patient use only. Disinfection efficacy studies were performed on the external meter materials by an outside commercial testing laboratory demonstrating complete inactivation of Duck hepatitis B virus- a surrogate of hepatitis B virus (HBV) with the chosen disinfectant, Clorox Healthcare Bleach Germicidal Wipes (EPA Registration #67619-12). A robustness study was also conducted by the sponsor demonstrating that there was no change in performance nor 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. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7. Electrical safety and electromagnetic compatibility (EMC) testing had been performed and the TelePM Gen2 blood glucose monitoring system was found to be compliant.
8. Software and cybersecurity documentation was reviewed and found to be acceptable.
9. Test strip Lot release: The test strip lot release protocol and acceptance criteria for the release of the TeleRPM blood glucose test strips for use with the TelePM Gen2 blood glucose monitoring system were reviewed and found to be acceptable.

VIII Proposed Labeling:

The labeling supports or 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.