



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

I Background Information:

A 510(k) Number

K200277

B Applicant

Livongo Health, Inc.

C Proprietary and Established Names

Livongo Blood Glucose Monitoring System (BG1000)

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:

Capillary whole blood glucose

C Type of Test:

Quantitative, Amperometric, Glucose Dehydrogenase (FAD-GDH)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Livongo Blood Glucose Monitoring System (BG1000) is composed of the Livongo Blood Glucose Meter (BG1000) and Livongo Blood Glucose Test Strips (BG1000).

The system is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips. The system is intended for self-testing by people with diabetes at home as an aid to monitor the effectiveness of diabetes control programs. The Livongo Blood Glucose Monitoring System (BG1000) is intended for single-patient use and should not be shared.

The system is for in vitro diagnostic use and is not intended for the diagnosis of or screening for diabetes, nor intended for use on neonates.

C Special Conditions for Use Statement(s):

- OTC - Over The Counter
- For In Vitro Diagnostic Use
- The Livongo meter should not be used to test critically ill patients.
- The Livongo meter should not be used to test neonates.
- The Livongo meter has not been evaluated for alternative Site Testing (AST). Only use blood from the fingertip.
- The Livongo Blood Glucose Monitoring System (BG1000) is only for self-testing and single patient use.
- Very high (above 70%) and very low (below 10%) hematocrit levels can cause false results. Talk to your doctor to find out your hematocrit level.
- The Livongo Blood Glucose Monitoring System (BG1000) has not been tested to work properly above 10,000 ft (3,048 meters).
- Blood samples from patients in shock, severe dehydration or a hyperosmolar state (with or without ketosis) have not been tested. It's not recommended to test those samples with the Livongo Blood Glucose Monitoring System (BG1000).
- This device 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.
- The Livongo Blood Glucose Monitoring System (BG1000) is not intended for the diagnosis of or screening for diabetes.

D Special Instrument Requirements:

Livongo Blood Glucose Meter (BG1000)

IV Device/System Characteristics:

A Device Description:

The Livongo Blood Glucose Monitoring System (BG1000) consist of the following:

Livongo Blood Glucose Meter (BG1000)
Livongo Blood Glucose Test Strips (BG1000)
Livongo Lancing Device
Livongo Lancets
Livongo Blood Glucose Control Solution Level 1 (sold separately) and Level 2
AC Adapter and USB Charger Set
Carrying Case
Instructions for use

The Livongo Blood Glucose Meter (BG1000) is a handheld device that incorporates features to aid in self-monitoring of blood glucose including tables, logs, and graphs. The blood glucose results are displayed on the screen and stored in the meter's memory, and may also be transmitted over a cellular network to a secure server.

The Livongo Blood Glucose Test Strips (BG1000) were previously cleared under k181527.

B Principle of Operation:

The Livongo Blood Glucose Monitoring System (BG1000) measures glucose amperometrically, and includes enzyme glucose dehydrogenase (FAD-GDH) and a redox mediator that electrochemically reacts with glucose in the sample to produce an electrical current. The current is proportional the glucose concentration.

C Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☒	☐
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:
Livongo Blood Glucose Meter (BG1000)
2. Specimen Identification:
There is no specimen identification function with this device. A capillary specimen is applied directly from the fingertip to the test strip.
3. Specimen Sampling and Handling:
There are no specific specimen sampling or handling considerations. Capillary blood as collected from the fingertip is applied directly to the test strip.
4. Calibration:
No user calibration is required.
5. Quality Control:
Livongo Glucose Control Solutions are used to confirm that the meter and test strips are working properly. Glucose control solutions are aqueous control solutions that contain known concentrations of glucose. Two levels are available (Level 1 and Level 2) for use with the systems. Level 2 is provided with the kit. Level 1 is sold separately. Instructions on how to order the control solutions and when to conduct control solution testing are included in the user manual. The meter will automatically detect the control solution and mark the test separately from blood glucose test results. An acceptable range for each control level is printed on the test strip vial label.

V Substantial Equivalence Information:

A Predicate Device Name(s):

On Call Sure Blood Glucose Monitoring System, On Call Sure Sync Blood Glucose Monitoring System

B Predicate 510(k) Number(s):

K181527

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>k200277</u>	<u>k181527</u>
Device Trade Name	Livongo Blood Glucose Monitoring System (BG1000)	On Call Sure Blood Glucose Monitoring System; On Call Sure Sync Blood Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	Quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip as an aid in monitoring the	Same

	effectiveness of the diabetes control program.	
Measurement range	40-600 mg/dL	Same
Enzyme	Glucose Dehydrogenase (FAD-GDH)	Same
General Device Characteristic Differences		
Patient sampling site	Fingertip only	Fingertip, forearm, and palm
Meter interface	Touch screen	Monochrome display and push buttons

VI Standards/Guidance Documents Referenced:

Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use, Guidance for Industry and Food and Drug Administration Staff. October 11, 2016.

CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Repeatability (within-run precision):

The sponsor performed a repeatability (within-run) precision study using venous whole blood samples adjusted to six different glucose concentrations (30-50, 51-110, 111-150, 151-250, 251-400, and 401-600 mg/dL). Each of the six samples was analyzed in replicates of 10 with three test strips lots and 10 meters for a total of 300 test results per glucose level. The results are summarized in the table below:

Glucose level	Average	SD	%CV
1	45.8	1.49	3.3%
2	78.2	2.33	3.0%
3	126.3	3.37	2.7%
4	192.9	5.13	2.7%
5	337.6	8.30	2.5%
6	491.7	12.37	2.5%

Intermediate Precision:

Intermediate (day to day) precision was performed using six levels of glucose control solution samples with target glucose concentrations of 40, 80, 130, 200, 325, and 500 mg/dL. Each of the six samples was tested in one run per day for 10 days using three test strip lots and 10 meters, with 1 replicate per meter for a total of 300 test results per glucose level. The results are summarized below:

Glucose level	Average	SD	%CV
1	46.3	1.41	3.0%
2	89.1	2.30	2.6%
3	141.5	4.08	2.9%
4	229.3	5.37	2.3%
5	359.2	7.88	2.2%
6	546.4	12.15	2.2%

2. Linearity:

Linearity was evaluated using venous whole blood samples adjusted to 10 concentrations spanning the measurement range with glucose concentrations of 25, 50, 80, 110, 170, 220, 330, 450, 550, and 650 mg/dL as measured by the comparator method, YSI 2300. Each sample was tested with 10 meters in replicates of 10 per meter using 3 test strip lots for a total of 100 results per sample and test strip lot. The linear regression results are presented below:

Strip Lot	Slope	Intercept	R ²
1	0.988	2.1	0.9968
2	0.980	0.5	0.9984
3	0.976	3.3	0.9974

The results of the linearity study support the claimed glucose measurement range of 40-600 mg/dL.

If a sample has glucose less than 40 mg/dL an error message is displayed by the meter which reads: Severely Low: < 40 mg/dL. If a sample has glucose greater than 600 mg/dL an error message is displayed by the meter which reads: Severely High: > 600 mg/dL. These error messages were validated using blood glucose samples outside the measuring range of the device to demonstrate that the error messages functioned as intended.

3. Analytical Specificity/Interference:

The information to support the analytical specificity performance was provided and found to be acceptable.

The following statements are listed in the product labeling.

- If you are taking a high dose of vitamin C (blood concentration > 3 mg/dL), the result from your meter may not be correct.
- Do not use during or soon after xylose absorption testing since xylose may cause inaccurate glucose results. Ask your doctor how long to wait before performing a glucose test.

4. Assay Reportable Range:

The assay reportable range is 40-600 mg/dL.

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

Traceability:

The system reports plasma-equivalent glucose values, and is calibrated by using the YSI 2300 STAT PLUS Glucose Analyzer, which is traceable to the NIST SRM 917b glucose reference material.

Test Strip Stability:

For the test strips, the labeling indicates a shelf life of 24 months and an open vial stability of 6 months when stored at the recommended storage conditions of 36°F-95°F (2-35°C) and 10-90% relative humidity. Protocols and acceptance criteria were reviewed and found to be acceptable to support the labeled shelf life and open vial stability claims.

6. Detection Limit:

The lower limit of the reportable range is based on the linearity study above (section A2).

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:

See lay user study below in section VII.C3.

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):

Method Comparison/Lay User Evaluation study

To assess the performance of Livongo Blood Glucose Monitoring System (BG1000) in the hands of the intended users, the sponsor conducted a user evaluation study consisting of 383 lay user participants who collected capillary samples from their fingertip and independently self-tested following only the product labeling in English. Greater than 10% of the participants were identified by questionnaire as a naïve users; i.e. not previously used any self-monitoring blood glucose system. Three test strip lots were used in the study. The results were analyzed by comparing the capillary blood glucose value obtained by the lay user with their system against a plasma glucose value measured in duplicate with a laboratory-based comparator method (YSI Model 2300 STAT PLUS Glucose Analyzer). The glucose concentrations across all samples ranged from 54 to 579 mg/dL, which includes 20 native samples < 80 mg/dL and 50 samples > 250 mg/dL as measured by the comparator method. The results were analyzed for differences with the comparator, and by regression analysis, and are summarized below:

Glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
10/14 (71.4%)	14/14 (100.0%)	14/14 (100.0%)

Glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
219/369 (59.3%)	331/369 (89.7%)	368/369 (99.7%)	369/369 (100.0%)

Combined glucose concentrations across the measuring range:

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
226/383 (59.0%)	343/383 (89.6%)	382/383 (99.7%)	383/383 (100.0%)

Results of linear regression analysis:

Slope	Intercept	R ²
1.021	-2.6	0.983

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 Livongo Blood Glucose Monitoring System.

Readability:

A Flesch-Kincaid readability assessment was conducted, and the results demonstrated that the Livongo Blood Glucose Monitoring System (BG1000) instructions for use are written for a reading level lower than 8th grade.

Extreme Glucose Values Study

A study was conducted to assess the performance of the device at the extremes of the measurement range. Patient samples were either glycolyzed or spiked with glucose, to achieve 73 capillary blood samples with glucose concentrations <80 mg/dL, and 66 capillary blood samples with glucose to concentrations >250 mg/dL. Results obtained on the candidate device were compared to those obtained on the comparator method, YSI 2300, and is summarized in the tables below:

Glucose concentration < 80 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
56 / 73 (76.7%)	73 / 73 (100.0%)	73 / 73 (100.0%)

Glucose concentration > 250 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
47 / 66 (71.2%)	65 / 66 (98.5%)	66 / 66 (100.0%)	66 / 66 (100.0%)

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The sponsor includes the following expected glucose values in their labeling:

Time	Range, mg/dL
Fasting and Before Meals	70 – 100
2 Hours After Meal	Less than 140

From: American Diabetes Association (Standards of Medical Care in Diabetes – 2018. Diabetes Care, January 2018, vol. 41, Supplement 1, S13-S27).

F Other Supportive Instrument Performance Characteristics Data:

1. Hematocrit Study

To evaluate the effect of hematocrit on the Livongo Blood Glucose Monitoring System (BG1000), venous blood samples were adjusted to hematocrit levels of 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65% and 70%. Each hematocrit level was tested at six glucose concentration levels (~40, ~80, ~130, ~200, ~325, and ~500 mg/dL). Each sample was tested in replicates of ten using 30 meters on each of three test strip lots for a total of 90 measurements per sample. Results were compared to results obtained using a laboratory-based comparator measurement (YSI 2300 STAT PLUS analyzer). The evaluation

of bias and percent bias relative to values obtained on the YSI 2300 STAT PLUS analyzer support that hematocrit concentrations of 10-70% do not impact test results.

2. Altitude Study

Information to support the claimed performance of the device at elevations up to 10,000 ft (3,048 m) was reviewed and found to be acceptable.

3. Sample Volume Study

A study was conducted to verify the minimum sample volume requirement for the test strip. Venous whole blood samples at three glucose levels (50-65, 100-120, and 200-250 mg/dL) were tested at five sample volumes (0.4, 0.5, 0.6, 0.7, and 0.8 μ L) using three test strip lots. Glucose results obtained with the candidate device were compared to values obtained using the comparator method (YSI 2300 STAT PLUS analyzer). The results of the study support the claimed minimum sample volume of 0.6 μ L. The results also demonstrated that with blood volumes below 0.6 μ L, an error message of insufficient sample volume functioned as intended.

4. Operating Conditions Study

The effect of combined operating temperature and relative humidity conditions on the Livongo Blood Glucose Monitoring System (BG1000) was evaluated using venous whole blood samples prepared at six glucose concentration levels (45.2, 103.0, 130.7, 202.4, 327.0, and 526.6 mg/dL). Test strips from 3 lots were exposed to one of 7 relative humidity (RH) and temperature conditions (10% RH/5°C, 10% RH/21°C, 10% RH/45°C, 90% RH/5°C, 90% RH/21°C, 90% RH/45°C, or 45% RH/21°C). The glucose results from the candidate device were compared to results obtained using the comparator method, YSI 2300 STAT PLUS, and support the claimed operating conditions of 10-90% RH and 41-113F (5-45°C).

5. 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.

6. Infection Control Studies

The Livongo Glucose Monitoring System (BG1000) is intended for single-patient use only. Disinfection efficacy studies were performed on the meter materials by an outside commercial laboratory, demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant: PDI Super Sani-Cloth Germicidal Disposable Wipe (EPA Registration number: 9480-4). Robustness studies were also performed by the sponsor using the Livongo Glucose Monitoring System demonstrating that there was no change in the performance of the system or in the external materials of the meter after 260 cycles of cleaning and disinfection using the chosen disinfectant. The robustness studies were designed to simulate cleaning and disinfecting over the five year single-patient use life of the meter. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7. Flex Studies

Drop testing, vibration testing, intermittent sampling, sample perturbation, and testing with used test strips were completed. The testing performed demonstrated that the device is robust

to these common use scenarios, and that the appropriate error messages are returned to the user if one of the situations has occurred.

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.