June 4, 2020

Livongo Health, Inc.
Jacob Gendler
Regulatory Affairs Project Manager
150 W. Evelyn Ave, Suite 150
Mountain View, CA 94041

Re: K200277
Trade/Device Name: Livongo Blood Glucose Monitoring System (BG1000)
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: May 2, 2020
Received: May 4, 2020

Dear Jacob Gendler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, M.T., Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200277

Device Name
Livongo Blood Glucose Monitoring System (BG1000)

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Premarket Submission
Livongo Blood Glucose Monitoring System (BG1000)

510(k) Summary

K200277

1. Submitter

Livongo Health, Inc.
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Phone: +1 (612) 418-4648
Email: jacob.gendler@livongo.com
Contact: Jacob Gendler, Regulatory Affairs Project Manager

Date Prepared: May 11, 2020

2. Device Information

Proprietary Name	Livongo Blood Glucose Monitoring System (BG1000)
Common Name	Blood Glucose Monitoring System
Class	II
Regulation	21 CFR §862.1345
Product Code	NBW; System, Test, Blood Glucose, Over The Counter

3. Predicate Device

On Call Sure / On Call Sure Sync Blood Glucose Monitoring System (K181527)

4. Device Description

The Livongo Blood Glucose Monitoring System (BG1000) is an Over-The-Counter (OTC) system designed for the self-monitoring of blood glucose by persons with diabetes in home settings to aid in their diabetes management. The system consists of the following components:

- Livongo Blood Glucose Meter (BG1000) ("Livongo meter")
- Livongo Blood Glucose Test Strips (BG1000) ("Livongo test strips")
- Livongo Lancing Device – class I accessory
- Livongo Lancets
- Livongo Level 1 Control Solution
- Livongo Level 2 Control Solution
- AC Adapter (wall charger) and USB Charger Set
- Carrying Case

The Livongo meter is a cellular-connected handheld device that monitors glucose in the blood to help with the management and treatment of diabetes. The meter also incorporates additional features to aid in self-monitoring of blood glucose including tables and logs, graphs. The blood glucose levels 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 test strips will be packaged in 50 count of strips in sealed vials.

The Livongo Control Solutions consist of an aqueous based mixture prepared with a known amount of glucose concentration. It is available in two levels, Level 1 and Level 2.

5. Indications 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 monitoring 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.

6. Comparison to Predicate Device

The table below compares the Livongo Blood Glucose Management System (BG1000) with the predicate device (K181527).

Feature	**This Device**	**Predicate Device (K181527)**
Trade Name	Livongo Blood Glucose Monitoring System (BG1000)	On Call Sure / On Call Sure Sync Blood Glucose Monitoring System
Meter Model No.	BG1000	OGM-211
Indications 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 monitoring 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 On Call Sure and On Call Sure Sync Blood Glucose Monitoring Systems are comprised of the On Call Sure or On Call Sure Sync Blood Glucose Meter and On Call Sure Blood Glucose Test Strips. The On Call Sure and On Call Sure Sync Blood Glucose Monitoring Systems are intended to be used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips, forearm and palm. The On Call Sure and On Call Sure Sync Blood Glucose Monitoring Systems are intended for self-testing by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control programs. The On Call Sure and On Call Sure Sync Blood Glucose Monitoring

Feature	This Device	Predicate Device (K181527)
	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.	Systems are intended for single-patient use and should not be shared. The On Call Sure and On Call Sure Sync Blood Glucose Monitoring Systems are for in vitro diagnostic use. The On Call Sure and On Call Sure Sync Blood Glucose Monitoring Systems are not intended for the diagnosis of or screening for diabetes, nor intended for use on neonates. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).
Detection Method	Amperometric electrochemical	Same
Enzyme	Glucose Dehydrogenase (FAD-GDH)	Same
Calibration Coding	Auto-coding	Same
Test Range	40 – 600 mg/dL	Same
Units of Measurement	mg/dL	Same
Result Calibration	Plasma-equivalent, calibrated by using YSI (Model 2300 STAT PLUS) Glucose Analyzer reference instrument, which is traceable to NIST reference standard.	Same
Memory	1000 records with time and date	Same
Day Average	7, 14, 30, 60 and 90-day averages	Same
Sample Type	Capillary whole blood	Same
Sample Sites	Fingertip only	Fingertip, forearm, palm
Sample Volume	0.6 µL	Same
Sample Test Time	5 seconds	Same
Hematocrit Range	10 – 70%	Same
Altitude Study	Up to 10000 feet	Same
Operating Temperature	41-113°F (5-45°C)	Same
Operating Relative Humidity	10–90%	Same
Automatic Shutoff	120 seconds	Same
Power Source	Rechargeable 3.85V lithium ion battery	Two CR 2032 3.0V coin cell batteries
Battery Charge Time	<4.5 hours	N/A

Feature	This Device	Predicate Device (K181527)
AC adapter	Yes	No
Meter Size	130 x 60 x 12.7 mm	90 x 60 x 16 mm
Meter Weight	142 g	72 g (with batteries installed)
Meter Color	Blue & white	Navy blue or black
Strip Ejector	No	Yes
Meter Screen Size	4”	2.25”
Meter User Interface	Touch-panel LCM	Monochrome display with push button interface
Camera	Yes (hardware support only)	No
Speaker	Yes	Same
Microphone	Yes (hardware support only)	No
Strip light	1	0
3-axis accelerometer	1 (hardware support only)	0
Vibrator motor	Yes (hardware support only)	No
Electrical Safety Testing	IEC 61010 compliant	Same
EMC Testing	IEC 60601-1-2 compliant	Same
Method Comparison/ User Evaluation	Per FDA guidance “Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use”	Same

7. Summary of Non-Clinical Performance

Design verification and validation testing was performed to ensure the Livongo Blood Glucose Monitoring System (BG1000) met design specifications and requirements. Testing is summarized below.

Within-Run Precision Evaluation

Ten replicate assays were each run on ten Livongo meters using three strip lots. Heparinized venous blood samples at six concentration levels were used in the testing. The results are summarized below.

Glucose Level	Mean	Standard Deviation or % CV
1	45.8 mg/dL	1.49 mg/dL
2	78.2 mg/dL	2.33 mg/dL
3	126.3 mg/dL	2.7%
4	192.9 mg/dL	2.7%
5	337.6 mg/dL	2.5%
6	491.7 mg/dL	2.5%

Intermediate Precision Evaluation

Ten replicate assays were each run on ten Livongo meters using test strips from three lots. Heparinized venous blood samples at six concentration levels were used in the testing. The results are summarized below.

Glucose Level	Mean	Standard Deviation or % CV
1	46.3 mg/dL	1.41 mg/dL
2	89.7 mg/dL	2.30 mg/dL
3	141.5 mg/dL	2.9%
4	229.3 mg/dL	2.3%
5	359.2 mg/dL	2.2%
6	546.4 mg/dL	2.2%

Linearity Evaluation

Blood samples were prepared to 42±2% hematocrit level and were run on 10 meters using test strips from three lots. Samples were prepared at eleven blood glucose concentration levels as shown in the table below.

Level	Glucose Concentration Level
25	20 -30 mg/dL
50	40 - 60 mg/dL
80	70 - 90 mg/dL
110	100 -120 mg/dL
170	160 -180 mg/dL
220	210 - 230 mg/dL
330	310 - 350 mg/dL
450	430 - 470 mg/dL
550	520 - 580 mg/dL
650	600 - 700 mg/dL

Linear regression analysis results are shown in the table below.

Strip Lot	Slope	Y-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 glucose measurement range of 40-600 mg/dL for the Livongo Blood Glucose Monitoring System (BG1000).

Interference – Hematocrit

Hematocrit interference was tested using whole blood samples that were prepared to hematocrit levels across the claimed hematocrit range at 5% intervals with six glucose concentration levels. Test strips from three strip lots were used for testing, with bias compared to a comparator method (YSI).

The bias of measurement was within ±10 mg/dL for glucose concentration level 1. For glucose concentration levels 2-6, the bias of measurement was within ±8%, and no individual value had a bias of greater than 15%, confirming accurate readings for the specified hematocrit range of 10%-70%.

Flex Studies

Flex studies were used to validate the insensitivity of the test system to performance variation due to factors that may contribute to erroneous results when used in home use settings rather than in laboratory or professional healthcare settings. The robustness of the system was validated through mechanical vibration and shock testing, operating conditions (temperature and humidity) testing, altitude effects testing, and stability testing. Additional sources of error that were tested included samples outside the measuring range, short sample detection, sample perturbation, intermittent sampling, and testing with used strips. In all of the tests, the system operated within its specified operating ranges even under stress conditions, and errors were correctly displayed when outside the meter's operating ranges.

Electromagnetic Interference and Electrical Safety

The system passed electrical and safety testing according to national and international standards including IEC 61010-1, IEC 61010-2-101, IEC 61000-3-2, IEC 61000-3-3, IEC 61000-4-2, and IEC 61000-4-8.

The li-ion battery is certified to IEC 62133.

The system passed EMC testing to national and international standards including IEC 60601-1-2, FCC 47 CFR 15 Part B, and PTCRB.

Software

Based on the FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 11, 2005, testing and documentation for Moderate level of concern software was completed.

8. Summary of Clinical Performance

A clinical (user evaluation) study was conducted with the intended user, lay persons using the Livongo Blood Glucose Monitoring System (BG1000) to evaluate in a simulated home environment. The study data were presented evaluating the system accuracy of the Livongo Blood Glucose Monitoring System (BG1000) compared to the YSI 2300 Stat Plus Glucose Analyzer (K913806). Study results indicated that non-professional, inexperienced lay persons were able to obtain blood glucose readings when using the Livongo Blood Glucose Monitoring System (BG1000) comparable to the comparator YSI 2300 obtained by trained technicians. In addition, the participating lay persons were questioned and responded as satisfied with the ease of operation by following the Instructions for Use in the User Guide and the overall performance of the Livongo Blood Glucose Monitoring System (BG1000).

9. Discussion of Substantial Equivalence

The results of bench performance and clinical performance testing demonstrate that the candidate device is substantially equivalent to the predicate device, On Call Sure / On Call Sure Sync Blood Glucose Monitoring System (K181527).