August 11, 2021

Abbott Diabetes Care, Inc.
Catherine Yang
Sr. Regulatory Affairs Manager
1360 South Loop Road
Alameda, California 94502

Re: K211102
Trade/Device Name: FreeStyle Libre 2 Flash Glucose Monitoring System
Regulation Number: 21 CFR 862.1355
Regulation Name: Integrated Continuous Glucose Monitoring System
Regulatory Class: Class II
Product Code: QLG
Dated: April 12, 2021
Received: April 13, 2021

Dear Catherine Yang:

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, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211102

Device Name
FreeStyle Libre 2 Flash Glucose Monitoring System

Indications for Use *(Describe)*

The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.

The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time.

The System is also intended to autonomously communicate with digitally connected devices. The System can be used alone or in conjunction with these digitally connected devices where the user manually controls actions for therapy decisions.

The System can be used with the FreeStyle Libre 2 Sensor (14 day) or the FreeStyle Libre 2 MediRx Sensor (10 day).

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.

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K211102

1.1 Submitter:

Abbott Diabetes Care, Inc.
1360 South Loop Road
Alameda, CA 94502

Contact: Catherine Yang
Title: Sr. Regulatory Affairs Manager
Phone: (510) 206-9452
Fax: (510) 864-4791

Date Prepared: April 12, 2021

1.2 Device Names and Classification:

Name of Device:	FreeStyle Libre 2 Flash Glucose Monitoring System
Common Name:	Integrated Continuous Glucose Monitoring System, Factory Calibrated, Not for use with automated insulin delivery systems
Regulatory Section(s):	21 CFR 862.1355, 21 CFR 862.1345
Classification:	Class II
Product Code(s):	QLG, NBW
Review Panel:	Clinical Chemistry

1.3 Predicate Device

Predicate Device:	FreeStyle Libre 2 Flash Glucose Monitoring System (K193371, cleared on June 12, 2020)
	This predicate device has not been subject to a recall

1.4 Indications for Use:

Indications for Use:

The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated.

The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time.

The System is also intended to autonomously communicate with digitally connected devices. The System can be used alone or in conjunction with these digitally connected devices where the user manually controls actions for therapy decisions.

The System can be used with the FreeStyle Libre 2 Sensor (14 day) or the FreeStyle Libre 2 MediRx Sensor (10 day).

Contraindications

- Automated Insulin Dosing: The System must not be used with automated insulin dosing (AID) systems, including closed loop and insulin suspend systems.

- MRI/CT/Diathermy: The System must be removed prior to Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The effect of MRI, CT scans, or diathermy on the performance of the System has not been evaluated. The exposure may damage the Sensor and may impact proper function of the device which could cause incorrect readings.

1.5 Device Description

Predicate Device

The FreeStyle Libre 2 Flash Glucose Monitoring System (K193371, cleared on June 12, 2020) is an integrated continuous glucose monitoring (iCGM) system that provides continuous glucose measurements every minute to provide glucose levels, trends, and real-time alarms capability to aid in the management of diabetes. The FreeStyle Libre 2 System consists of two primary components: a Sensor that transmits via Bluetooth Low Energy (BLE), and a BLE enabled display device (Reader). User initiated RFID scanning of the Sensor via Reader provides the user with real-time glucose measurements (glucose values) accompanied by trend information (glucose arrows) and historical glucose information (glucose graph). Users may use the Sensor glucose results and information provided by the System in making treatment decisions. The System also provides configurable alarms designed to warn the user of Low Glucose, High Glucose or Signal Loss. The system is intended for single-patient use at home and requires a prescription.

FreeStyle Libre 2 Sensor

- The Sensor is single use, disposable, and powered by a silver oxide battery. The Sensor is provided as two secondary components, Sensor Applicator and Sensor Pack (electron beam sterilized device) which are used to assemble and apply the Sensor to the back of the user's arm. During Sensor application, the sensor tail is inserted about 5.5 millimeters below the surface of the skin through the guidance of a needle. The needle is retracted back into the applicator after insertion, and the Sensor remains attached to the skin with a medical grade adhesive. The Sensor continuously measures glucose concentration in interstitial fluid and has an 8-hour memory capacity. The Sensor is factory calibrated, does not require fingerstick calibration, and can be worn for up to 14 days.

FreeStyle Libre 2 Reader

- The Reader is a small handheld device that is powered by a lithium-ion rechargeable battery and uses RFID communication to start new Sensors and to scan Sensors to display and record data and uses BLE communication to issue alarms that notify the user to scan his/her sensor when glucose values pass a high or low glucose threshold. The Reader also has a built-in strip port with blood glucose functionality (that is intended to work with the FreeStyle Precision Neo Blood Glucose test strips, cleared under K171941), and a user interface that includes event logging features.

Subject Device

The proposed subject device is a modified FreeStyle Libre 2 Flash Glucose Monitoring System that adds compatibility with the FreeStyle Libre 2 MediRx Sensor, which can be worn for up to 10 days. The FreeStyle Libre 2 MediRx Sensor design is unchanged from that of the predicate FreeStyle Libre 2 Sensor, which remains compatible with the modified System. In addition, the Sensor glucose algorithm and Reader design of the modified System remain unchanged from those of the predicate.

The alternate 10-day wear duration of the FreeStyle Libre 2 MediRx Sensor is achieved by changing a Sensor configuration parameter at manufacturing, which is detected by the predicate Reader to automatically determine the wear duration and accordingly adjust the user interface display of remaining Sensor wear time and ensure the Sensor cannot report data beyond the configured wear duration. In addition, each Sensor type has an end of life parameter, which determines when the Sensor will automatically shut down. This functionality is already built into the Sensor and Reader and was validated as part of previously conducted software validation under K193371.

Other than the differences related to wear duration, the FreeStyle Libre 2 MediRx Sensor is identical to the predicate Sensor, and the predicate Reader functions as intended with either the predicate FreeStyle Libre 2 Sensor (14 day) or FreeStyle Libre 2 MediRx Sensor (10 day).

Test Principle

Both the predicate and modified FreeStyle Libre 2 Flash Glucose Monitoring Systems use a Sensor that incorporates a subcutaneously implanted electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF) and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to an electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the subcutaneous space. The electrical current signal is converted to a glucose value (in mg/dL) for display to the user on the handheld Reader.

1.6 Substantial Equivalence

A. Predicate Device Name:

FreeStyle Libre 2 Flash Glucose Monitoring System

B. Predicate 510(k) Number(s):

K193371

C. Comparison with Predicate:

The similarities and differences between the subject and the predicate device are highlighted in the tables below.

Similarities		
Item	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K193371)**	**Subject Device: Modified FreeStyle Libre 2 Flash Glucose Monitoring System**
Intended Use	The System is intended to monitor interstitial fluid glucose concentrations and communicate with digitally connected devices for the purpose of managing a disease or condition related to glycemic control.	Same
Intended Use Population	Persons with diabetes age 4 and older	Same
Device type	Integrated CGM	Same
Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction	Same
Sample Type	Interstitial fluid	Same
Enzyme	Glucose oxidase	Same
Test Range	40 to 400 mg/dL	Same
Clinical Application	Management of diabetes mellitus	Same
Clinical Setting/Sites of Use	Home use	Same
Data Displayed	Current glucose value, current glucose trend, graph with recent glucose history, user entered events	Same
Primary display device	FreeStyle Libre 2 Reader	Same

Similarities (Continued)		
Item	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K193371)**	**Subject Device: Modified FreeStyle Libre 2 Flash Glucose Monitoring System**
Alerts and Alarms	Low Glucose Alarm, High Glucose Alarm, Signal Loss Alarm, Scan Error, Sensor Error	Same
Wireless communication protocol	Near Field Communication (NFC): (13.56 MHz RFID) Bluetooth Low Energy (BLE): 4.0	Same
BLE Communication range	20 feet unobstructed	Same
Sensor Glucose Algorithm	FreeStyle Libre 2 Reader algorithm	Same
Method of Sensor Activation	RFID communication	Same
Method of Data transfer from Sensor	RFID – upon user-initiated scan BLE – for glucose data to support glucose alarms	Same
Glucose reading update interval	Every 1 minute	Same
Trend Graph Glucose History	8 hours, 24-hour graph and other reports can be used to view logged data	Same
Glucose Trend Arrow	↑, > +2 mg/dL/min ↗, +1 and +2 mg/dL/min →, -1 to +1 mg/dL/min ↘, -2 to -1 mg/dL/min ↓, < -2 mg/dL/min	Same
Situations where fingerstick test is required to confirm sensor reading (adjunctive use)	• The user's symptoms do not match the glucose values displayed by the device. • The device does not show a glucose value • During the first 12 hours of wear during which the check blood glucose icon is displayed	Same
Compatibility with connected devices	Compatible with digitally connected devices where the user manually controls actions for therapy decisions	Same
Sensor calibration	Factory calibrated	Same
Anatomical Sensor wear locations	Back of the upper arm	Same
Sensor warmup time	1 hour	Same
FreeStyle Libre 2 Sensor life	Up to 14 days (automatic sensor shut off)	Same
Storage Conditions (Sensor Kit)	Temperature: 36°F – 82°F Humidity: 10-90% RH	Same
Retail packaging configuration for FreeStyle Libre 2 Sensor Kits	One (1) packaging configuration option: • One (1) Sensor Kit carton with no additional outer carton	Same

Differences		
Item	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K193371)**	**Subject Device: Modified FreeStyle Libre 2 Flash Glucose Monitoring System**
Indications for Use	The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated. The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time. The System is also intended to autonomously communicate with digitally connected devices. The System can be used alone or in conjunction with these digitally connected devices where the user manually controls actions for therapy decisions.	The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated. The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time. The System is also intended to autonomously communicate with digitally connected devices. The System can be used alone or in conjunction with these digitally connected devices where the user manually controls actions for therapy decisions. The System can be used with the FreeStyle Libre 2 Sensor (14 day) or the FreeStyle Libre 2 MediRx Sensor (10 day).
Compatible Sensors	FreeStyle Libre 2 Sensor	FreeStyle Libre 2 Sensor or FreeStyle Libre 2 MediRx Sensor
FreeStyle Libre 2 MediRx Sensor Life	N/A	Up to 10 days (automatic sensor shut off)
Retail packaging configuration for FreeStyle Libre 2 MediRx Sensor Kits	N/A	Two (2) packaging configuration options: • One (1) Sensor Kit carton with no additional outer carton • Three (3) individual Sensor Kit cartons packaged within an outer carton

1.7 Summary of Performance Testing

All product development activities were performed in compliance with the Design Control requirements per 21 CFR 820.30. The implementation of the modified FreeStyle Libre 2 Flash Glucose Monitoring System is evaluated, verified, and validated under the requirements of Abbott Diabetes Care's (ADC's) internal design control process, which establishes a process for design and manufacturing changes to be assessed, tested and implemented appropriately.

The following summary of performance testing supports substantial equivalence to the predicate device:

- Software Testing

  The predicate Freestyle Libre 2 Reader is designed to detect the Sensor configuration parameter, which is stored in the Sensor and set at manufacturing. The predicate Reader uses this Sensor configuration parameter to automatically determine the wear duration and accordingly adjust the user interface display of remaining Sensor wear time and ensure the Sensor cannot report data beyond the configured wear duration. In addition, each Sensor type has an end of life parameter, which determines when the Sensor will automatically shut down. This functionality is already built into the predicate Sensor and Reader and was validated as part of previously conducted software validation under K193371.

  The FreeStyle Libre 2 MediRx Sensor differs from the predicate FreeStyle Libre 2 Sensor only with respect to the Sensor configuration parameter. There are no other changes made to the subject device design, cybersecurity, software, glucose algorithm, or other functionality to allow for compatibility of the Reader with the FreeStyle Libre 2 MediRx Sensor.

- Clinical Performance Evaluation

  Clinical data from the adult and pediatric iCGM clinical studies that supported clearance of the predicate device were re-analyzed to show that use of the subject device with the FreeStyle Libre 2 MediRx Sensor for a 10-day wear duration meets the iCGM special controls for clinical performance set forth in 21 CFR 862.1355.

The following supportive performance characteristics were established in the predicate device in K193371 and are not affected by the introduction of the FreeStyle Libre 2 MediRx Sensor in this 510(k):

- Sterilization
- Biocompatibility
- Mechanical Testing
- Electrical Safety and Electromagnetic Compatibility
- Environmental Testing
- Shelf-Life Stability
- Packaging Integrity/Shipping Integrity

- Human Factors
- Manufacturing Controls
- Cybersecurity
- Interoperability
- RF Wireless Communication

1.8 Proposed Labeling

The subject device labeling informs users of the System compatibility with the predicate FreeStyle Libre 2 Sensor and proposed FreeStyle Libre 2 MediRx Sensor along with the corresponding wear durations. The System User's Manual was updated to include a separate section on the performance data of the FreeStyle Libre 2 Flash Glucose Monitoring System when used with FreeStyle Libre 2 MediRx Sensor (10-day wear duration). In addition, separate Sensor Kit retail packaging and branding are introduced for the FreeStyle Libre 2 MediRx Sensor Kit.

The proposed labeling satisfies the requirements of 21 CFR Part 801, 21 CFR Part 807. 87(e), 21 CFR Part 809, and the 21 CFR Part 862.1355 special controls.

1.9 Conclusion

The modified FreeStyle Libre 2 Flash Glucose Monitoring System has the same intended use and clinical application as the predicate device. Based on the performance testing and data provided in this pre-market notification, the subject device and predicate have been shown to be substantially equivalent.