November 22, 2021

Abbott Diabetes Care Inc.
Ono Bacani
Regulatory Affairs Project Manager
1360 South Loop Rd.
Alameda, California 94502

Re: K210943
Trade/Device Name: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App)
Regulation Number: 21 CFR 862.1355
Regulation Name: Integrated Continuous Glucose Monitoring System
Regulatory Class: Class II
Product Code: QLG, NBW
Dated: March 29, 2021
Received: March 30, 2021

Dear Ono Bacani:

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)*
K210943

Device Name
FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App)

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 (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.

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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.

510(k) Number: K210943

1.1 Submitter:

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

Contact: Ono Bacani
Title: Sr. Manager, Regulatory Affairs
Phone: 510-239-2622
Fax: (510) 864-4791

Date Prepared: November 14, 2021

1.2 Device Names and Classification:

Name of Device:	FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App)
Common Name:	Integrated Continuous Glucose Monitoring System, Factory Calibrated, Not for use with automated insulin delivery systems
Regulatory Section:	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 (with FreeStyle Libre 2 App), K201761 cleared on July 30, 2021 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

The FreeStyle Libre 2 Flash Glucose Monitoring System with the FreeStyle Libre 2 App – Android (herein referred to as the 'FreeStyle Libre 2 System' or 'System') is an integrated continuous glucose monitoring system (iCGM) 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 System requires a prescription and is intended for home use. The System consists of the following components: a Sensor which transmits via Bluetooth Low Energy (BLE), a BLE enabled display device (Reader), and an Android or iOS mobile app (FreeStyle Libre 2 App) downloaded to a compatible smartphone. Scanning of the Sensor via Reader or App provides the user with real-time glucose measurements (glucose values) accompanied by trend information (glucose arrows) and historical glucose information (glucose graph). The user may make treatment decisions based in part on the Sensor glucose

results provided by the System. The System also provides configurable alarms designed to warn the user of Low Glucose, High Glucose or Signal Loss.

FreeStyle Libre 2 Sensor (14 day) and FreeStyle Libre 2 MediRx Sensor (10 day)

- 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 and does not require fingerstick calibration. The FreeStyle Libre 2 Sensor can be worn for up to 14 days while the FreeStyle Libre 2 MediRx Sensor can be worn for up to 10 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.

FreeStyle Libre 2 App (iOS and Android)

- The App's design, functionality and user interface is based on the handheld Reader. When downloaded to a compatible smartphone, the App uses RFID communication to start new Sensors and to scan Sensors to display and record data and uses BLE communication to issue alarms. As a mobile application, the FreeStyle Libre 2 App allows connectivity with cloud-based applications. The FreeStyle Libre 2 App is an alternative primary display for the System and does not interact with the Reader. The FreeStyle Libre 2 App is distributed using the Apple App Store and Google Play Store, and a list of compatible devices is accessible in the App via the Help feature or product website.

1.6 Substantial Equivalence

A. Predicate Device Name:
FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App)

B. Predicate 510(k) Number(s):
K201761

C. Comparison with Predicate:
The similarities and differences between the subject and the predicate device are highlighted in the tables below.

Similarities		
Item	**Subject Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App)**	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App) (K201761)**
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
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).	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.
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
Test Range	40 to 400 mg/dL	Same

Similarities		
Item	**Subject Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App)**	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App) (K201761)**
Clinical Application	Management of diabetes mellitus	Same
Intended Use Population	Persons with diabetes age 4 and older	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
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
Optional Alarms	Low Glucose Alarm, High Glucose Alarm, Signal Loss Alarm For Low and High Glucose alarms, a user-initiated action is required to see glucose reading	Same
Mandatory Alarms	The App includes mandatory alarms for Urgent Low Glucose, Replace Sensor, Sensor Ended, App Stopped (iOS only) These alarms are mandatory (set to 'On') and cannot be modified by the user. For Urgent Low Glucose alarm, a user-initiated action is required to see glucose reading	Same
Scan-Based Alerts	Scan Error, Sensor Error, Replace Sensor, Sensor Ended	Same
Wireless communication protocol with version number	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	The app uses the same algorithm as the FreeStyle Libre 2 Reader	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

Similarities		
Item	**Subject Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App)**	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App) (K201761)**
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
Method of communication and connectivity with cloud-based applications	The Reader can communicate and connect with LibreView through the USB port connection with the desktop computer. App only: can communicate wirelessly to LibreView. Through LibreView, can communicate to LibreLinkUp App	Same
Sensor calibration	Factory calibrated	Same
Compatible Sensor warmup time	1 hour	Same
Trend graph glucose history capabilities	8 hours, 24-hour graph and other reports can be used to view logged data	Same
Blood Glucose Meter	While using the App, user must have access to a blood glucose monitoring system as the App does not provide one.	Same

Differences		
Item	**Subject Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App)**	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App) (K201761)**
Primary display device(s)	FreeStyle Libre 2 Reader or FreeStyle Libre 2 App (iOS or Android)	FreeStyle Libre 2 Reader or FreeStyle Libre 2 App (iOS)
Compatible Sensors	FreeStyle Libre 2 Sensor (14 day) FreeStyle Libre 2 MediRx Sensor (10 day)	FreeStyle Libre 2 Sensor (14 day)
Compatible operating systems and hardware platform for the App	Compatible with Apple iOS; Android operating system and Android-enabled smartphones	Compatible with Apple iOS

1.7 Comparison of Technological Characteristics with the Predicate Device

Amperometric measurement of glucose concentration (via glucose oxidase chemical reaction) in the interstitial fluid is the technological principle for both the subject and predicate devices. The electrochemical sensor is held in place with an adhesive pad and incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the subcutaneous space. The compatible receiver converts the electrical current signal to a glucose value (in mg/dL) for display to the user.

At a high-level, the subject and predicate devices are based on the following technological elements:

- Compatibility with FreeStyle Libre 2 Sensor (14 day) and FreeStyle Libre 2 MediRx Sensor (10 day)
- Use of NFC interface for starting new Sensors and scanning Sensors to display glucose readings
- Use of BLE interface to issue alarms
- Use of software algorithm for conversion of the raw glucose measurements from the Sensor to calculate glucose results
- Inclusion of software interface to wirelessly communicate with cloud-based application (App only)

The following technological differences exist between the subject and predicate devices:

- The differences between the FreeStyle Libre 2 App (Android) and FreeStyle Libre 2 App (iOS) in operating systems and compatible NFC- and BLE-enabled smartphones were evaluated as part of System performance testing, and the App incorporates software controls to detect variations in smartphone settings and smartphone operating system configurations that may impact alarm delivery.

1.8 Summary of Performance Testing

The following performance testing was conducted to support substantial equivalence:

- Software Verification and Validation – software verification and validation testing was conducted in accordance with established specifications and IEC 62304 and documentation was provided as recommended by FDA Guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," May 11, 2005. Results of executed protocols met the acceptance criteria and therefore support that the Android App software is acceptable for its intended use.

- Human Factors – human factors testing of the System was conducted in accordance with ANSI/AAMI/IEC 62366, IEC 60601-1-6, and FDA Guidance document "Applying Human Factors and Usability Engineering to Medical Devices," dated February 3, 2016. Results demonstrated that the System met usability requirements.

- Wireless Coexistence – the System underwent coexistence testing consistent with AAMI TIR69 and ANSI C63.27 and included test challenges from in-band interference sources defined in ANSI C63.27, as well as other expected wireless interference sources from the intended use environment. Test results showed the System could tolerate interference generated by these RF interfering devices and still meet the target performance criteria.

- Cybersecurity – ADC has provided cybersecurity risk management documentation for the System that includes analysis of confidentiality, integrity, and availability for data, information and software related to the System. For each identified threat and vulnerability risk event scenario, risk assessment of impact to confidentiality integrity, and availability was performed and documented within the cybersecurity risk management documentation. Appropriate risk mitigation controls have been implemented and tested.

- Electrical Safety and Electromagnetic Compatibility (EMC) – the System underwent electrical safety and EMC evaluation. Results of the evaluation demonstrated that the System complies with electrical safety and EMC requirements per IEC 60601-1:2005(r)2012 and IEC 60601-1-2:2014, respectively.

The following supportive performance characteristics were established in the predicate device in K201761 and are not affected by the introduction of the Android FreeStyle Libre 2 App in this 510(k):

- Sterilization
- Biocompatibility
- Mechanical Engineering
- Environmental Testing
- Shelf-Life Stability
- Packaging Integrity/Shipping Integrity
- Interoperability
- Clinical Performance - the Android App utilizes the identical algorithm and implements the same wireless interfaces with the Sensor as used by the Reader and iOS App. As the Android App calculates glucose information identically to the predicate device, no additional clinical data beyond that provided in K193371 and K211102 were used in this 510(k) to support a determination of substantial equivalence.

1.9 Conclusion

The subject device has the identical intended use and clinical application as the predicate device. The difference in technological characteristics as a result of introducing the Android FreeStyle Libre 2 App as an alternate primary display option, have been addressed through risk control measures to provide reasonable assurance of the safety and effectiveness of the modified System. The Reader and the FreeStyle Libre 2 App (iOS and Android) utilize the identical algorithm and implement the same wireless interfaces with the Sensor. System performance testing (using Sensors and representative smartphone models with the App installed) confirmed that the device met all specified criteria, which supports that the System provides accurate, secure, and reliable glucose readings in accordance with the iCGM special controls. Based on the performance testing and data provided in this pre-market notification, the subject and predicate device have been shown to be substantially equivalent.