May 26, 2022

Abbott Diabetes Care Inc.
Rodney Huang
Director, Regulatory Affairs
1360 South Loop Road
Alameda, California 94502

Re: K213996
Trade/Device Name: FreeStyle Libre 3 Continuous 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 8, 2022
Received: April 11, 2022

Dear Rodney Huang:

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); 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 Toxicological Devices
OHT7: Office of Invitro Diagnostics
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)*

k213996

Device Name

FreeStyle Libre 3 Continuous Glucose Monitoring System

Indications for Use *(Describe)*

The FreeStyle Libre 3 Continuous Glucose Monitoring System is a real time continuous glucose monitoring (CGM) device with 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.

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) 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: K213996

Submitter

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

Contact: Rodney Huang
Title: Director, Regulatory Affairs
Phone: (510) 239-2614
Fax: (510) 864-4791

Date Prepared: May 16, 2022

Device Names and Classification

Name of Device:	FreeStyle Libre 3 Continuous Glucose Monitoring System
Common Name:	Integrated Continuous Glucose Monitoring System, Factory Calibrated, Not for use with automated insulin delivery systems
Regulatory Section:	21 CFR 862.1355
Classification:	Class II
Product Code(s):	QLG
Review Panel:	Clinical Chemistry

Predicate Device

Predicate Device:	FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App) (K210943)
	The predicate device has not been subject to a recall

Indications for Use

Indications for Use

The FreeStyle Libre 3 Continuous Glucose Monitoring System is a real time continuous glucose monitoring (CGM) device with 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.

Contraindication

- 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.

Device Description

The FreeStyle Libre 3 Continuous Glucose Monitoring System (herein referred to as the 'FreeStyle Libre 3 System' or 'System') is an integrated continuous glucose monitoring system (iCGM) that provides real time continuous glucose measurements every minute to provide glucose levels, trends, and alarms. 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), and a mobile application, FreeStyle Libre 3 App, downloaded to a compatible smartphone running on Android operating system. The FreeStyle Libre 3 System 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 fixed and configurable alarms designed to warn the user of Low Glucose, High Glucose, or Signal Loss.

FreeStyle Libre 3 Sensor

- The Sensor is single use, disposable, and powered by a silver oxide battery. The Sensor is provided through a Sensor Applicator (which includes an electron beam sterilized sub-component) which is used to apply the Sensor to the back of the user's arm. The Sensor continuously measures glucose concentration in interstitial fluid and has a 14-day memory capacity. The Sensor is factory calibrated, does not require fingerstick calibration, and can be worn for up to 14 days.

FreeStyle Libre 3 App (Android)

- The FreeStyle Libre 3 App design, functionality and user interface is based on the FreeStyle Libre 2 Android app of the predicate device. When downloaded to a compatible Android-enabled smartphone, the FreeStyle Libre 3 App uses Near Field Communication to start new Sensors and BLE communication to display glucose data and issue alarms based on the measurements calculated by the Sensor. As a mobile application, the FreeStyle Libre 3 App allows connectivity with cloud-based applications. The FreeStyle Libre 3 App is distributed using the Google Play Store and a list of compatible devices is accessible in the App via the Help feature or product website.

Substantial Equivalence

A. Predicate Device Name

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

B. Predicate 510(k) Number(s)

K210943

C. Comparison with Predicate

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

Similarities		
Device	**Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System**	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App) (K210943)**
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
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
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	Near Field Communication (NFC)	Same
Wireless Communication Protocol	NFC: 13.56 MHz RFID Bluetooth Low Energy (BLE)	Same
Sensor Glucose Algorithm	ADC Glucose Algorithm established for the predicate device	Same
Glucose Reading Update Interval	Every 1 minute	Same
Glucose History	Graph and other reports can be used to view logged data	Same
Glucose Trend Arrows	↑, > +2 mg/dL/min ↗, +1 to +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	Same

Similarities		
Device	**Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System**	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App) (K210943)**
	• During the first 12 hours of wear during which the check blood glucose icon is displayed	
Mandatory Alarms	Glucose Alarms: Urgent Low Glucose System Alarms: Replace Sensor, Sensor Ended, Check Sensor These alarms are mandatory (set to 'On') and cannot be turned off or modified by the user. It will always sound regardless of the phone sound and vibe or Do Not Disturb settings.	Same Note: The Check Sensor condition is checked during the NFC scan, and detects when a Sensor has not been activated.
Optional Alarms	Glucose Alarms: Low Glucose Alarm, High Glucose Alarm System Alarm: Signal Loss Alarm	Same
Blood Glucose Meter (BGM)	While using the App, user must have access to a blood glucose monitoring system as the App does not provide one.	Same
Method of Communication and Connectivity with Cloud-based Applications for the App	App can communicate wirelessly to LibreView. Through LibreView, can communicate to LibreLinkUp App	Same
Compatibility with Connected Devices	Compatible with digitally connected devices where the user manually controls actions for therapy decisions	Same
Compatible Operating Systems for the Android App	The App is compatible with Android operating system (OS) and Android-enabled smartphones.	Same
Sensor Calibration	Factory Calibrated	Same
Compatible Sensor Warmup time	1 hour	Same

Differences		
Device	**Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System**	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App) (K210943)**
Indications for Use	The FreeStyle Libre 3 Continuous Glucose Monitoring System is a real time continuous glucose monitoring (CGM) device with 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).
System Components	On-body Sensor (No Sensor Applicator assembly required by user prior to applying the Sensor) FreeStyle Libre 3 App	On-body Sensor (User assembles Sensor Applicator and Sensor Container prior to applying the Sensor) FreeStyle Libre 2 App or FreeStyle Libre 2 Reader
Primary display device	FreeStyle Libre 3 App (Android)	FreeStyle Libre 2 App (iOS or Android) or

Differences		
Device	**Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System**	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App) (K210943)**
		FreeStyle Libre 2 Reader
Compatible Sensor Life	FreeStyle Libre 3 Sensor (14 day)	FreeStyle Libre 2 Sensor (14 day) FreeStyle Libre 2 MediRx Sensor (10 day)
Sensor Dimension	2.9 mm height / 21 mm diameter	5 mm height / 30 mm diameter
Location of Glucose Algorithm	Sensor	Receiver (Reader or App)
Method of Data Transfer from Sensor	Bluetooth Low Energy (BLE). Data automatically transfers without user initiated scan (streaming data).	BLE for glucose data transfer to issue alarms. User-initiated scan via NFC required to display glucose data
BLE Communication Range	33 feet unobstructed	20 feet unobstructed
Information provided with Glucose Alarm	Alarm type, glucose result and trend arrow	Alarm type

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 Sensor is held in place with an adhesive pad and incorporates a subcutaneously implanted sensor component and associated electronics. The electrochemical sensor component uses 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 Sensor converts the electrical current signal to a glucose value (in mg/dL) for display to the user on the App.

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

- Compatibility with system-specific Sensor
- Use of BLE interfaces for wireless communication with the Sensor
- Use of NFC interface for starting new Sensors
- 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 authorized cloud-based applications (App only for the predicate)

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

- The predicate device requires NFC interface for scanning Sensors to display glucose readings.
- Glucose alarms with the subject device includes trend arrow and glucose reading; the predicate device only displays the alarm type and the user is required to scan the Sensor to view the glucose result.

Summary of Performance Testing

The following performance characteristics were confirmed to support substantial equivalence:

- Sterility – Electron beam sterilization validation of the Sensor Applicator, which contains the introducer needle and sensor tail, was performed per ISO11137-1 and ISO 11137-2. Sterilization validation confirmed that the Sterility Assurance Level (SAL) of 10^{-6} is achieved with the minimum sterilization dose of 25 kGy. The sterilization dose was established by the VDmax25 method described in ISO 11137-2.

- Shelf-Life, Packaging Integrity, and Shipping – Device shelf life and packaging integrity over the shelf life was demonstrated by subjecting test units to worst case sealing parameters, sterilization parameters, and shipping configuration. Units were also conditioned through a worst case sequence of storage, handling and transit challenges prior to testing. Attributes related to seal integrity, user accessibility, and device functionality including sterile barrier system integrity met acceptance criteria.

- Electrical Safety - The basic safety and essential performance of the FreeStyle Libre 3 System was conducted to demonstrate compliance to IEC 60601-1: 2005(r)2012, IEC 60601-1-6:2010+A1:2013, and IEC 60601-1-11:2015.

- Electromagnetic Compatibility – Electromagnetic compatibility (EMC) testing was performed for the FreeStyle Libre 3 System to verify that the system is able to withstand the electromagnetic interference and emissions in compliance with IEC 60601-1-2 and IEC CISPR 11. Wireless coexistence testing was performed to confirm that the subject device remains functional and perform within acceptable limits while in the presence of common radiating electronic devices in accordance with FDA Guidance "*Radio Frequency Wireless Technology in Medical Devices*." The subject device 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. The FreeStyle Libre 3 System also successfully demonstrated compliance with Federal Communication Commission (FCC) Regulations Part 15.225 and Part 15.247, and Federal Aviation Administration (FAA) Advisory Circular RTCA DO-160.

- Mechanical Engineering – The subject device underwent performance testing at the System level as well as on individual components of the Sensor Applicator. The test results showed that mechanical, electrical, and functional testing all met the acceptance criteria.

- Biocompatibility – Biocompatibility evaluation and testing in accordance with ISO10993-1 and FDA Guidance "*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process*," was performed to demonstrate biocompatibility of the device.

- 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 "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*." Results of executed protocols met the acceptance criteria and therefore support that the System's embedded software is acceptable for its intended use.

- 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 accordance with FDA Draft Guidance "*Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*." 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.

- Clinical Performance –ADC conducted a bridging clinical study to demonstrate comparability of the performance of the FreeStyle Libre 3 System to the predicate FreeStyle Libre 2 System, cleared under K210943. The subject device calculates glucose information identically to the predicate device, and the combined System accuracy of the FreeStyle Libre 3 System and FreeStyle Libre 2 System met the iCGM special controls requirements per 21 CFR 862.1355.

- Human Factors – ADC conducted a risk analysis of the design and user interface in accordance with ANSI/AAMI/IEC 62366, IEC 60601-1-6, and FDA Guidance "*Applying Human Factors and Usability Engineering to Medical Devices*." The analysis demonstrated that the design changes implemented for the subject device meet usability requirements for its intended use.

- Interoperability – The subject device incorporated an approach for interoperability developed in alignment with FDA Guidance "Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices."

Conclusion

The FreeStyle Libre 3 Continuous Glucose Monitoring System has the identical intended use and clinical application as the predicate device. The differences in technological characteristics have been addressed through risk control measures to provide reasonable assurance of the safety and effectiveness of the FreeStyle Libre 3 System. System performance testing 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 device and predicate device have been shown to be substantially equivalent.