February 21, 2023

Abbott Diabetes Care, Inc.
Simon Yuan
Official Correspondent
1360 South Loop Road
Alameda, CA 94502

Re: K223537
Trade/Device Name: FreeStyle Libre 2 Flash Glucose Monitoring System, 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, NBW
Dated: November 21, 2022
Received: November 23, 2022

Dear Simon Yuan:

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,

Paula Caposino -S

Digitally signed by Paula Caposino -S
Date: 2023.02.21 11:19:41 -05'00'

Paula Caposino, Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro 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)*
K223537

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K223537

Device Name
FreeStyle Libre 3 Continous 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.

Abbott
Diabetes Care

1. 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: K223537

1.1 Submitter:

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

Contact: Simon Yuan
Title: Principal Regulatory Affairs Specialist
Phone: (510) 206-6719
Fax: (510) 864-4791

Date Prepared: February 17, 2023

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:	21 CFR 862.1355, 21 CFR 862.1345
Classification:	Class II
Product Code(s):	QLG, NBW
Review Panel:	Clinical Chemistry

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

1.3 Predicate Device

Predicate Device:	FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App), K210943 cleared November 22, 2021
	FreeStyle Libre 3 Continuous Glucose Monitoring System, K213996 and K212132 cleared May 26, 2022

1.4 Indications for Use

1.4.1 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.

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.

1.4.2 FreeStyle Libre 3 Continuous Glucose Monitoring System

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.

1.5 Device Description

The FreeStyle Libre 2 and FreeStyle Libre 3 are integrated continuous glucose monitoring (iCGM) Systems designed to be used alone or in conjunction with digitally connected devices. The FreeStyle Libre 2 System consists of a Sensor and either a Reader or the FreeStyle Libre 2 App downloaded to a compatible smartphone as a primary display device. The FreeStyle Libre 3 System consists of a Sensor and the FreeStyle Libre 3 App downloaded to a compatible smartphone as a primary display device. Both Systems can communicate glucose data and other information wirelessly and securely to and from these digitally connected devices as described below:

- Wireless communication from the FreeStyle Libre 2 Sensor or FreeStyle Libre 3 Sensor directly to an interoperable receiver device, which connects with the Sensor using the near field communication (NFC) and Bluetooth Low Energy wireless interfaces provided by the Sensor
- The FreeStyle Libre 2 App or FreeStyle Libre 3 App communicates through the cloud to another software device, such as LibreView.

Compared to the respective predicate devices, the proposed subject devices include an additional software component, the Libre Data Sharing API. The Libre Data Sharing API is a cloud-based application programming interface (API) that enables communication of glucose data including alarms through the cloud from the FreeStyle Libre 2 System or FreeStyle Libre 3 System to authorized client software on digitally connected devices. The data transmitted by the API to authorized client software can be used for specific and permitted use cases, including non-medical device applications, medical device data analysis, CGM secondary display alarm, active patient monitoring, and treatment decisions. Use of the Libre Data Sharing API and the CGM information it transmits is limited by the indications for use of the iCGM systems with which it is used.

The Libre Data Sharing API does not have any command or control over the client software, nor does it allow for the client software to have any command or control over the FreeStyle Libre 2 or FreeStyle Libre 3 Systems. Additionally, glucose data and alarms from the connected iCGM system are not modified or manipulated by the Libre Data Sharing API through its transmission to the authorized client software.

The display device of the connected FreeStyle Libre 2 or FreeStyle Libre 3 Systems, which directly receives the data from the Sensor, continues to serve as a primary display device for the glucose data and alarms. The current components of the FreeStyle Libre 2 and FreeStyle Libre 3 Systems (sensor/applicator and primary display devices) have not been modified as a result of the added the Libre Data Sharing API.

1.5.1 FreeStyle Libre 2 Flash Glucose Monitoring System

The FreeStyle Libre 2 Flash Glucose Monitoring System is an 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 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:

- 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 NFC 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 or Android)

- The App's design, functionality and user interface is based on the handheld Reader. When downloaded to a compatible smartphone, the App uses NFC 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.

1.5.2 FreeStyle Libre 3 Continuous Glucose Monitoring System

The FreeStyle Libre 3 Continuous Glucose Monitoring System is an 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 BLE, and an Android or iOS mobile app (FreeStyle Libre 3 App) downloaded to a compatible smartphone. 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 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 (iOS or Android)

- When downloaded to a compatible smartphone, the FreeStyle Libre 3 App uses NFC 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 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

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

1.6.1 FreeStyle Libre 2 Flash Glucose Monitoring System

Device	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App), K210943**	**Subject Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with Libre Data Sharing API), K223537**
Trade Name	FreeStyle Libre 2 Flash Glucose Monitoring System	Same

Device	Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App), K210943	Subject Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with Libre Data Sharing API), K223537
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
Clinical Application	Management of diabetes mellitus	Same

Device	Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App), K210943	Subject Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with Libre Data Sharing API), K223537
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	NFC communication	Same
Method of Data Transfer from Sensor	NFC – 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	NFC: 13.56 MHz RFID Bluetooth Low Energy (BLE)	Same
BLE Communication Range	20 feet unobstructed	Same
Sensor Glucose Algorithm	ADC Glucose Algorithm	Same
Glucose Reading Update Interval	Every 1 minute	Same

Device	Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App), K210943	Subject Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with Libre Data Sharing API), K223537
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 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 • 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
Primary Display Device(s)	FreeStyle Libre 2 Reader or FreeStyle Libre 2 App (iOS or Android)	Same

Device	Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App), K210943	Subject Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with Libre Data Sharing API), K223537
Compatible Operating Systems and Hardware Platform for the App	Compatible with Apple iOS; Android operating system and Android-enabled smartphones	Same
Interoperability	Designed to enable communication of glucose data and other information wirelessly and securely to and from digitally connected devices as described below: • Wireless communication from the FreeStyle Libre 2 Sensor directly to interoperable receiver devices, which connect with the Sensor using the NFC and BLE wireless interfaces provided by the Sensor • The FreeStyle Libre 2 App communicates through the cloud to another software device.	The FreeStyle Libre 2 System with Libre Data Sharing API allows the same wireless and secure communications as the predicate device and additionally enables users to communicate iCGM data wirelessly and securely to and from digitally connected devices (client software) through a cloud-based communication method, the Libre Data Sharing API. An interoperability communication plan will be provided to potential partners/developers. This interoperability communication plan specifies expectations, requirements and interface specifications to ensure the data is transmitted and received securely and reliably by the digitally connected devices. Software verification conducted to ensure predefined requirements including but not limited to data confidentiality, integrity, and timely availability were fulfilled.

1.6.2 FreeStyle Libre 3 Continuous Glucose Monitoring System

Device	Predicate Device: FreeStyle Libre 3 Continuous Glucose Monitoring System, K213996 and K212132	Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System (with Libre Data Sharing API), K223537
Trade Name	FreeStyle Libre 3 Continuous Glucose Monitoring System	Same

Device	Predicate Device: FreeStyle Libre 3 Continuous Glucose Monitoring System, K213996 and K212132	Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System (with Libre Data Sharing API), K223537
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 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.	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

Device	Predicate Device: FreeStyle Libre 3 Continuous Glucose Monitoring System, K213996 and K212132	Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System (with Libre Data Sharing API), K223537
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
BLE Communication Range	33 feet unobstructed	Same
Method of Data Transfer from Sensor	Bluetooth Low Energy (BLE). Data automatically transfers without user initiated scan (streaming data).	Same
Sensor Glucose Algorithm	ADC Glucose Algorithm	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 • During the first 12 hours of wear during which the check blood glucose icon is displayed	Same

Device	Predicate Device: FreeStyle Libre 3 Continuous Glucose Monitoring System, K213996 and K212132	Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System (with Libre Data Sharing API), K223537
Mandatory Alarms	Glucose Alarms: Urgent Low Glucose System Alarms: Replace Sensor, Sensor Ended, Check Sensor, App Stopped (iOS only) 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
Optional Alarms	Glucose Alarms: Low Glucose Alarm, High Glucose Alarm System Alarm: Signal Loss Alarm	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
Primary display device	FreeStyle Libre 3 App	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 and Hardware Platform for the App	The App is compatible with Compatible with Apple iOS and Android operating system (OS) and Android-enabled smartphones.	Same
Sensor Calibration	Factory Calibrated	Same
Compatible Sensor Warmup time	1 hour	Same

Device	Predicate Device: FreeStyle Libre 3 Continuous Glucose Monitoring System, K213996 and K212132	Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System (with Libre Data Sharing API), K223537
Interoperability	Designed to enable communication of glucose data and other information wirelessly and securely to and from digitally connected devices as described below: • Wireless communication from the FreeStyle Libre 3 Sensor directly to interoperable receiver devices, which connect with the Sensor using the NFC and BLE wireless interfaces provided by the Sensor • The FreeStyle Libre 3 App communicates through the cloud to another software device.	The FreeStyle Libre 3 System with Libre Data Sharing API allows the same wireless and secure communications as the predicate device and additionally enables users to communicate iCGM data wirelessly and securely to and from digitally connected devices (client software) through a cloud-based communication method, the Libre Data Sharing API. An interoperability communication plan will be provided to potential partners/developers. This interoperability communication plan specifies expectations, requirements and interface specifications to ensure the data is transmitted and received securely and reliably by the digitally connected devices. Software verification conducted to ensure predefined requirements including but not limited to data confidentiality, integrity, and timely availability were fulfilled.

1.7 Comparison of Technological Characteristics with Predicate Device

The proposed FreeStyle Libre 2 and FreeStyle Libre 3 Systems have the same technological characteristics as their respective predicate devices, which measure glucose concentration in the interstitial fluid through amperometric measurement via glucose oxidase chemical reaction.

The proposed subject devices include an additional software component, the Libre Data Sharing API, which enables ‘other functions’, as defined in FDA guidance "Multiple Function Device Products: Policy and Considerations - Guidance for Industry and Food and Drug Administration Staff", to communicate iCGM data with authorized client software for specific and permitted use cases in accordance with the cleared intended use environments.

The primary display devices of the FreeStyle Libre 2 or FreeStyle Libre 3 Systems remain unchanged and will continue to act as the primary display device and issue glucose alarms to the user when glucose levels are outside of a target zone. The Libre Data Sharing API does not have any command or control over the client software, nor does it allow for the client software to have any command or control over the FreeStyle Libre 2 and FreeStyle Libre 3 Systems. Additionally, glucose data and alarms from the FreeStyle Libre 2 and FreeStyle Libre 3 Systems are not modified or manipulated by the Libre Data Sharing API through its secured transmission to the authorized client software. Therefore, the functionality of the additional Libre Data Sharing API software component has no impact on the safety or effectiveness of the device function of the FreeStyle Libre 2 and FreeStyle Libre 3 Systems.

1.8 Summary of Performance Testing

The proposed subject devices with the Libre Data Sharing API were verified and validated according to ADC's internal design control process and in accordance with the applicable special controls for integrated continuous glucose monitoring systems. The testing demonstrated that the subject devices conform to the iCGM special controls per 21 CFR 862.1355 and that they performed according to specifications and met their technological and performance criteria.

1.9 Conclusion

The proposed FreeStyle Libre 2 and FreeStyle Libre 3 Systems are substantially equivalent to their respective predicates as they are the same with regards to intended use and indications for use and there are no differences in technological characteristics that raise different questions of safety and effectiveness. 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.