April 13, 2023

Abbott Diabetes Care, Inc.
Katherine Doll Kanne
Principal Regulatory Affairs Specialist
1360 South Loop Road
Alameda, CA 94502

Re: K223435
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: QBJ, NBW
Dated: March 13, 2023
Received: March 14, 2023

Dear Katherine Doll Kanne:

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 V. Caposino -S
Digitally signed by Paula V. Caposino -S
Date: 2023.04.13 13:12:26 -04'00'

Paula Caposino, Ph.D.
Acting Deputy Division 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)*
K223435

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 2 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, including automated insulin dosing (AID) systems. The System can be used alone or in conjunction with these digitally connected devices for the purpose of managing diabetes.

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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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)*
K223435

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 2 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, including automated insulin dosing (AID) systems. The System can be used alone or in conjunction with these digitally connected devices for the purpose of managing diabetes.

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.

5. 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: K223435

5.1 Submitter:

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

Contact: Katherine Doll Kanne
Title: Principal Regulatory Affairs Specialist
Phone: (612) 394-9209
Fax: (510) 864-4791

Date Prepared: April 13, 2023

5.2 Device Names and Classification:

Name of Device:	FreeStyle Libre 3 Continuous Glucose Monitoring System
Common Name:	Integrated Continuous Glucose Monitoring System, Factory Calibrated
Regulatory Section:	21 CFR 862.1355, 21 CFR 862.1345
Classification:	Class II
Product Code(s):	QBJ, NBW
Review Panel:	Clinical Chemistry

Name of Device:	FreeStyle Libre 2 Flash Glucose Monitoring System
Common Name:	Integrated Continuous Glucose Monitoring System, Factory Calibrated
Regulatory Section:	21 CFR 862.1355, 21 CFR 862.1345
Classification:	Class II
Product Code(s):	QBJ, NBW
Review Panel:	Clinical Chemistry

5.3 Predicate Device

Predicate Devices:	Freestyle Libre 3 Continuous Glucose Monitoring System and FreeStyle Libre 2 Flash Glucose Monitoring System (K222447)

5.4 Indications for Use:

5.4.1 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 2 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, including automated insulin dosing (AID) systems. The System can be used alone or in conjunction with these digitally connected devices for the purpose of managing diabetes.

Contraindication
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.

5.4.2 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 2 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, including automated insulin dosing (AID) systems. The System can be used alone or in conjunction with these digitally connected devices for the purpose of managing diabetes.

Contraindication
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.

5.5 Device Description

The FreeStyle Libre 3 Continuous Glucose Monitoring System (hereinafter also referred to as 'FSL3 System') and FreeStyle Libre 2 Flash Glucose Monitoring System (hereinafter also referred to as the 'FSL2 System') are integrated continuous glucose monitoring (iCGM) systems that provide continuous glucose measurements every minute to provide glucose levels, trends, and real-time alarms capability to aid in the management of diabetes. The FSL2 and FSL3 Systems also provide configurable alarms designed to warn the user of Low Glucose, High Glucose or Signal Loss. The user may make treatment decisions based in part on the Sensor glucose results provided by both Systems. The FSL2 and FSL3 Systems require a prescription and are intended for home use.

The FSL3 System consists of the FreeStyle Libre 3 Sensor and either the FreeStyle Libre 3 Reader or the FreeStyle Libre 3 App (iOS and Android) downloaded to a compatible smartphone as a primary display device. The FSL3 Reader and FSL3 App do not interact with each other.

The FSL2 System consists of the FreeStyle Libre 2 Sensor and either the FreeStyle Libre 2 Reader or the FreeStyle Libre 2 App (iOS and Android) downloaded to a compatible smartphone as a primary display device. The FSL2 Reader and FSL2 App do not interact with each other.

Both the FSL2 and FSL3 Systems are compatible with the Libre Data Sharing API cleared in K223537. The display device of the connected FSL2 or FSL3 Systems, which directly receives the data from the Sensor, continues to serve as a primary display device for the glucose data and alarms.

5.5.1 FreeStyle Libre 3 Continuous Glucose Monitoring System

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. During Sensor application, the sensor tail is inserted 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 a 15-day memory capacity. The Sensor is factory calibrated, does not require fingerstick calibration, and can be worn for up to 15 days.

FreeStyle Libre 3 App (iOS and Android)

- When downloaded to a compatible smartphone, the FreeStyle Libre 3 App uses Near Field Communication (NFC) 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.

FreeStyle Libre 3 Reader

- The FreeStyle Libre 3 Reader is a small handheld device that is powered by a lithium-ion rechargeable battery and uses NFC communication to start new Sensors and BLE communication to display glucose data and 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.

5.5.2 FreeStyle Libre 2 Flash Glucose Monitoring System

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 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 15 days.

FreeStyle Libre 2 App (iOS and Android)

- When downloaded to a compatible smartphone, the FreeStyle Libre 2 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 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.

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.

5.6 Substantial Equivalence

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

5.6.1 FreeStyle Libre 3 Continuous Glucose Monitoring System

Similarities		
	Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System	**Predicate Device: FreeStyle Libre 3 Continuous Glucose Monitoring System (K222447)**
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 2 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, including automated insulin dosing (AID) systems. The System can be used alone or in conjunction with these digitally connected devices for the purpose of managing diabetes.	Same
Intended Use Population	Persons with diabetes age 2 and older	Same
Device Type	Integrated CGM	Same
Compatible operating systems and hardware platform for App	App is compatible with iOS and Apple smartphone; Android operating system (OS) and Android-enabled smartphones.	Same
Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction	Same

Similarities		
	Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System	**Predicate Device: FreeStyle Libre 3 Continuous Glucose Monitoring System (K222447)**
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
Method of Sensor Activation	Near Field Communication (NFC)	Same
Wireless communications protocol	NFC: 13.56 MHz RFID Bluetooth Low Energy (BLE)	Same
Method of Data Transfer from Sensor	Bluetooth Low Energy (BLE). Data automatically transfers without user initiated scan (streaming data).	Same
BLE Communication Range	33 feet unobstructed	Same
Sensor Glucose Algorithm	ADC Glucose Algorithm established for the predicate device	Same
Location of glucose algorithm	Sensor	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
App method of communication and connectivity with cloud-based applications	App can communicate wirelessly to LibreView. Through LibreView, can communicate to LibreLinkUp App.	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		
	Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System	**Predicate Device: FreeStyle Libre 3 Continuous Glucose Monitoring System (K222447)**
	• During the first 12 hours of wear during which the check blood glucose icon is displayed	
Mandatory Alarms	Glucose Alarm: Urgent Low Glucose System Alarm: Replace Sensor, Sensor Ended, Check Sensor, App Stopped (iOS only)	Same
Optional Alarms	Glucose Alarms: Low Glucose Alarm, High Glucose Alarm System Alarm: Signal Loss Alarm	Same
Information provided with glucose alarm	Alarm type, glucose result and trend arrow	Same
Compatible Sensors	FreeStyle Libre 3 Sensor	Same
Sensor Calibration	Factory Calibrated	Same
Compatible Sensor Warmup time	1 hour	Same
Compatible Sensor Life	Up to 15 days (automatic Sensor shut off)	Same
Anatomical Sensor wear locations	Back of the upper arm	Same
Sensor Tail Dimension	5.5 mm depth, 0.3 mm width	Same
Application Programming Interfaces (APIs)	Enables users to share their glucose data with authorized client software. Can communicate iCGM data wirelessly and securely to and from digitally connected devices (client software) through a cloud-based communication method.	Same

Differences		
	Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System	**Predicate Device: FreeStyle Libre 3 Continuous Glucose Monitoring System (K222447)**
System Components	FreeStyle Libre 3 Sensor FreeStyle Libre 3 App (iOS or Android) FreeStyle Libre 3 Reader	FreeStyle Libre 3 Sensor FreeStyle Libre 3 App (iOS or Android)
Primary display device	FreeStyle Libre 3 App (iOS or Android) or FreeStyle Libre 3 Reader	FreeStyle Libre 3 App (iOS or Android) only
Reader method of communication and connectivity with cloud-based applications	Reader can communicate and connect with LibreView through the USB port connection with the desktop computer.	No Reader
Blood Glucose Meter (BGM)	An integrated BGM is provided with the Reader While using the App, user must have access to a blood glucose monitoring system as the App does not provide one.	No Reader While using the App, user must have access to a blood glucose monitoring system as the App does not provide one.
Silent Mode Feature	App user has option to silence the Urgent Low Glucose Alarm, Low Glucose Alarm, High Glucose Alarm and Signal Loss Alarm. This feature is turned off by default but can be turned on by the user for a maximum of 6 hours.	No Silent Mode feature

5.6.2 FreeStyle Libre 2 Flash Glucose Monitoring System

Similarities		
	Subject Device: FreeStyle Libre 2 Flash Glucose Monitoring System	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K222447)**
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 2 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, including automated insulin dosing (AID) systems. The System can be used alone or in conjunction with these digitally connected devices for the purpose of managing diabetes.	Same
Intended Use Population	Persons with diabetes age 2 and older	Same
Device Type	Integrated CGM	Same
Compatible operating systems and hardware platform for App	App is compatible with iOS and Apple smartphone; Android operating system (OS) and Android-enabled smartphones.	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
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

Similarities		
	Subject Device: FreeStyle Libre 2 Flash Glucose Monitoring System	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K222447)**
Method of Sensor Activation	Near Field Communication (NFC)	Same
Wireless communications protocol	NFC: 13.56 MHz RFID Bluetooth Low Energy (BLE)	Same
Method of Data Transfer from Sensor	BLE for glucose data transfer to issue alarms. User-initiated scan via NFC required to display glucose data.	Same
BLE Communication Range	20 feet unobstructed	Same
Sensor Glucose Algorithm	ADC Glucose Algorithm established for the predicate device	Same
Location of glucose algorithm	Receiver (App or Reader)	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
Method of communication and connectivity with cloud-based applications	App can communicate wirelessly to LibreView. Through LibreView, can communicate to LibreLinkUp App. Reader can communicate and connect with LibreView through the USB port connection with the desktop computer.	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

Similarities		
	Subject Device: FreeStyle Libre 2 Flash Glucose Monitoring System	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K222447)**
Mandatory Alarms	Glucose Alarm: Urgent Low Glucose System Alarm: Replace Sensor, Sensor Ended, Check Sensor, App Stopped (iOS only) For Urgent Low Glucose alarm, a user-initiated action is required to see glucose reading.	Same
Optional Alarms	Glucose Alarms: Low Glucose Alarm, High Glucose Alarm System Alarm: Signal Loss Alarm For Low and High Glucose alarms, a user-initiated action is required to see glucose reading.	Same
Compatible Sensors	FreeStyle Libre 2 Sensor	Same
Sensor Calibration	Factory Calibrated	Same
Compatible Sensor Warmup time	1 hour	Same
Compatible Sensor Life	Up to 15 days (automatic Sensor shut off)	Same
Anatomical Sensor wear locations	Back of the upper arm	Same
Sensor Tail Dimension	5.5 mm depth, 0.3 mm width	Same
Blood Glucose Meter	An integrated BGM is provided with the Reader. While using the App, user must have access to a blood glucose monitoring system as the App does not provide one.	Same
Application Programming Interfaces (APIs)	Enables users to share their glucose data with authorized client software. Can communicate iCGM data wirelessly and securely to and from digitally connected devices (client software) through a cloud-based communication method.	Same

Differences		
	Subject Device: FreeStyle Libre 2 Flash Glucose Monitoring System	**Predicate Device: FreeStyle Libre 2 Continuous Glucose Monitoring System (K222447)**
Silent Mode Feature	App user has option to silence the Urgent Low Glucose Alarm, Low Glucose Alarm, High Glucose Alarm and Signal Loss Alarm. This feature is turned off by default but can be turned on by the user for a maximum of 6 hours.	No Silent Mode feature

5.7 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 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 electrical current signal is converted to a glucose value (in mg/dL) for display to the user on the compatible receiver.

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

- Use of NFC interface for starting new Sensors
- Use of BLE interface to issue alarms
- Use of software algorithm for conversion of Sensor raw glucose measurements to calculate glucose results
- Display of glucose results from FreeStyle Libre 2 Sensors after a user-initiated scan via NFC. Automatic display of glucose results from FreeStyle Libre 3 Sensors without a user-initiated scan.
- Inclusion of software interface to wirelessly communicate with cloud-based application (App only)
- Interoperability specification provided to authorized partners to allow compatibility with AID systems
- Libre Data Sharing API to communicate iCGM data with authorized client software for specific and permitted use cases in accordance with the cleared intended use environments

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

- The subject device FreeStyle Libre 3 System includes the FreeStyle Libre 3 Reader, which is a dedicated medical device, as an alternate primary display device to the FreeStyle Libre 3 App installed on a compatible smartphone, which is a multifunctional platform.
- The subject device FreeStyle Libre 3 App and FreeStyle Libre 2 App include a Silent Mode feature to silence the Urgent Low Glucose Alarm, Low Glucose Alarm, High Glucose Alarm and Signal Loss Alarm. This feature is turned off by default but can be turned on by the user for a maximum of 6 hours. The predicate devices do not include the Silent Mode feature.

5.8 Summary of Performance Testing

The following performance characteristics were evaluated to support substantial equivalence:

- Sterility – Electron beam sterilization validation in relation to 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 – Electrical Safety testing demonstrated that the basic safety and essential performance of the System is in 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 demonstrated 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 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 and evaluation was conducted in accordance with 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 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 the October 2014 FDA 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 –The subject device calculates glucose information identically to the predicate device. System accuracy was demonstrated to meet 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."

5.9 Conclusion

The FreeStyle Libre 3 Continuous Glucose Monitoring System and the FreeStyle Libre 2 Flash Glucose Monitoring System have the same intended use as the predicate devices. 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 devices and predicate device have been shown to be substantially equivalent.