April 23, 2024

Abbott Diabetes Care Inc.
Sapna Ghelani
Regulatory Affairs Project Manager
1360 South Loop Road
Alameda, California 94202

Re: K233537
Trade/Device Name: FreeStyle Libre 3 Continuous Glucose Monitoring System; FreeStyle Libre 2 Flash Glucose Monitoring System
Regulation Number: 21 CFR 862.1355
Regulation Name: Integrated Continuous Glucose Monitoring System
Regulatory Class: Class II
Product Code: QBJ, QLG, NBW
Dated: March 18, 2024
Received: March 19, 2024

Dear Sapna Ghelani:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
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)*
K233537

Device Name
FreeStyle Libre 2 Flash Glucose Monitoring System

Indications for Use *(Describe)*

Libre 2 Sensor users:
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.

Libre 2 Plus Sensor users:
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.

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
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"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)*
K233537

Device Name
FreeStyle Libre 3 Continuous Glucose Monitoring System

Indications for Use *(Describe)*

Libre 3 Sensor users:
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.

Libre 3 Plus Sensor users:
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)

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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: K233537

5.1 Submitter:

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

Contact: Sapna Ghelani
Title: Regulatory Affairs Project Manager
Phone: (805) 750-2721
Fax: (510) 864-4791

Date Prepared: April 21, 2024

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, QLG, 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, QLG, 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 (K223435)

5.4 Indications for Use:

5.4.1 FreeStyle Libre 3 Continuous Glucose Monitoring System

Libre 3 Sensor users:
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.

Libre 3 Plus Sensor users:
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

Diathermy: Remove all parts of your System before high-frequency electrical heat (diathermy) treatment. The effect of diathermy on the System hasn't been tested. The exposure may damage the Sensor, which could impact proper device function and cause inaccurate readings.

Automated Insulin Dosing: Libre 3 Sensors must not be used with automated insulin dosing (AID) systems, including closed loop and insulin suspend systems.

5.4.2 FreeStyle Libre 2 Flash Glucose Monitoring System

Libre 2 Sensor users:
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.

Libre 2 Plus Sensor users:
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

Diathermy: Remove all parts of your System before high-frequency electrical heat (diathermy) treatment. The effect of diathermy on the System hasn't been tested. The exposure may damage the Sensor, which could impact proper device function and cause inaccurate readings.

Automated Insulin Dosing: Libre 2 Sensors must not be used with automated insulin dosing (AID) systems, including closed loop and insulin suspend systems.

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 subject FSL3 System consists of a sensor (the FreeStyle Libre 3 Sensor (FSL3 Sensor) or FreeStyle Libre 3 Plus Sensor (FSL3 Plus Sensor)) and a primary display device (the FreeStyle Libre 3 Reader (FSL3 Reader) or the FreeStyle Libre App (FSL App) [iOS and Android] downloaded to a compatible phone). The FSL3 Reader and the FSL App do not interact with each other.

The subject FSL2 System consists of a sensor (the FreeStyle Libre 2 Sensor (FSL2 Sensor) or FreeStyle Libre 2 Plus Sensor (FSL2 Plus Sensor)) and a primary display device (the FreeStyle Libre 2 Reader (FSL2 Reader) or the FSL App (iOS and Android) downloaded to a compatible phone). The FSL2 Reader and FSL 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

<u>FreeStyle Libre 3 Sensor and FreeStyle Libre 3 Plus Sensor</u>

- 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, is factory calibrated, and does not require fingerstick calibration. The FSL3 Sensor has a 14-day memory capacity and can be worn for up to 14 days. The FSL3 Plus Sensor has a 15-day memory capacity and can be worn for up to 15 days.

<u>FreeStyle Libre App</u>

- When downloaded to a compatible phone, the FSL App uses Near Field Communication (NFC) to start new sensors and uses Bluetooth Low Energy (BLE) to receive glucose data from the sensor. The user can view current glucose information, trend information, historical information and alarms on the app. The FSL App is compatible with the FSL3

family of sensors (includes FSL3 Sensor and FSL3 Plus Sensor). As a mobile application, the FSL App allows connectivity with cloud-based applications. The FSL App is distributed using the Apple App Store and Google Play Store and a list of compatible phones is accessible in the app via the Help feature or FreeStyle Libre consumer website.

FreeStyle Libre 3 Reader

- The FSL3 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 and FreeStyle Libre 2 Plus 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 and does not require fingerstick calibration. The FSL2 Sensor can be worn for up to 14 days. The FSL2 Plus Sensor can be worn for up to 15 days.

FreeStyle Libre App

- When downloaded to a compatible phone, the FSL App uses NFC to start new sensors and uses BLE to receive glucose data from the sensor. The user can view current glucose information, trend information, historical information and alarms on the app. The FSL App is compatible with the FSL2 family of sensors (includes FSL2 Sensor and FSL2 Plus Sensor). As a mobile application, the FSL App allows connectivity with cloud-based applications. The FSL App is distributed using the Apple App Store and Google Play Store and a list of compatible phones is accessible in the app via the Help feature or FreeStyle Libre consumer 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. The reader 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.

Similarities			
Item	**Predicate Devices (K223435)** • **FreeStyle Libre 2 Flash Glucose Monitoring System** • **FreeStyle Libre 3 Continuous Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 2 Flash Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 3 Continuous Glucose Monitoring System**
Compatible Sensor[1]	FSL2 System FreeStyle Libre 2 Sensor FSL3 System FreeStyle Libre 3 Sensor	FreeStyle Libre 2 Plus Sensor FreeStyle Libre 2 Sensor	FreeStyle Libre 3 Plus Sensor FreeStyle Libre 3 Sensor
Compatible Sensor Life	Up to 15 days (Additionally, Predicate FSL2 System is compatible with FSL2 Sensor with 14 day sensor life and predicate FSL3 System is compatible with FSL3 Sensor with 14 day sensor life)	Same	Same

[1] ADC decided to rebrand the FSL2 Sensors and FSL3 Sensors with a modified sensor tail (K223435) as FreeStyle Libre 2 Plus Sensor and FreeStyle Libre 3 Plus Sensor, respectively. This is a change in brand name only.

Similarities			
Item	**Predicate Devices (K223435)** • **FreeStyle Libre 2 Flash Glucose Monitoring System** • **FreeStyle Libre 3 Continuous Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 2 Flash Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 3 Continuous 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. (Predicate FSL2 System is compatible with legacy FSL2 Sensor with 14 day sensor life)	Same	NA

Similarities			
Item	**Predicate Devices (K223435)** • **FreeStyle Libre 2 Flash Glucose Monitoring System** • **FreeStyle Libre 3 Continuous Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 2 Flash Glucose Monitoring System**	**Subject Device:** **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. (Predicate FSL3 System is compatible with FSL3 Sensor with 14 day sensor life)	NA	Same

Similarities			
Item	**Predicate Devices (K223435)** • **FreeStyle Libre 2 Flash Glucose Monitoring System** • **FreeStyle Libre 3 Continuous Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 2 Flash Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 3 Continuous Glucose Monitoring System**
Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction	Same	
Device type	Integrated CGM	Same	
Intended Use Population	Persons with diabetes age 2 and older (Additionally, predicate FSL2 System is compatible with legacy FSL2 Sensor with intended use population of age 4 and older, and predicate FSL3 System is compatible with FSL3 Sensor with intended use population of age 4 and older)	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			
Item	**Predicate Devices (K223435)** • **FreeStyle Libre 2 Flash Glucose Monitoring System** • **FreeStyle Libre 3 Continuous Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 2 Flash Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 3 Continuous Glucose Monitoring System**
Wireless Communication Protocol	Near Field Communication (NFC): 13.56 MHz RFID Bluetooth Low Energy (BLE)	Same	
Method of Sensor Activation	Near Field Communication (NFC): 13.56 MHz RFID	Same	
Mandatory Alarms	Glucose Alarm: Urgent Low Glucose System Alarm: Replace Sensor, Sensor Ended, Check Sensor (Note: Check Sensor is an alarm for FSL3 System whereas Check Sensor is not considered an alarm for the FSL2 System where the condition is checked during the NFC scan and detects when a sensor has not been activated).	Same	
Optional Alarms	Glucose Alarms: Low Glucose Alarm, High Glucose Alarm System Alarm: Signal Loss Alarm	Same	
Silent Mode	All App users have option to silence the Urgent Low Glucose Alarm, Low Glucose Alarm, High Glucose Alarm, and the Signal Loss Alarm. This feature is turned off by default but can be turned on by the user for a maximum of 6 hours.	Same	

Similarities			
Item	**Predicate Devices (K223435)** • **FreeStyle Libre 2 Flash Glucose Monitoring System** • **FreeStyle Libre 3 Continuous Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 2 Flash Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 3 Continuous Glucose Monitoring System**
Scan-Based Alerts	FSL2 System only: Scan Error, Sensor Error, Replace Sensor, Sensor Ended, Check Sensor	Same as predicate FSL2 System	N/A
BLE Communication Range	FSL2 System: 20 feet unobstructed FSL3 System: 33 feet unobstructed	Same as predicate FSL2 System	Same as predicate FSL3 System
Method of Data Transfer for Backfill Data Gap from Signal Loss	FSL2 System NFC – upon user-initiated scan FSL3 System BLE – data automatically transfers without user-initiated scan (streaming data).	Same as predicate FSL2 System	Same as predicate FSL3 System
Glucose Algorithm	ADC Glucose Algorithm	Same	
Location of Glucose Algorithm	FSL2 System: Receiver FSL3 System: Sensor	Same as predicate FSL2 System	Same as predicate FSL3 System
Glucose Reading Update Interval	Every 1 minute	Same	

Similarities			
Item	**Predicate Devices (K223435)** • **FreeStyle Libre 2 Flash Glucose Monitoring System** • **FreeStyle Libre 3 Continuous Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 2 Flash Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 3 Continuous Glucose Monitoring System**
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	Same	
Sensor Calibration	Factory calibrated	Same	
Compatible Sensor Warmup Time	1 hour	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	

Similarities			
Item	**Predicate Devices (K223435)** • **FreeStyle Libre 2 Flash Glucose Monitoring System** • **FreeStyle Libre 3 Continuous Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 2 Flash Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 3 Continuous Glucose Monitoring System**
Anatomical Sensor Wear Locations	Back of the upper arm	Same	
Compatible Operating Systems and Hardware Platform	App is compatible with: • iOS operating system and Apple iPhone • Android operating system and Android-enabled phones	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	
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, the Libre Data Sharing API.	Same	

Differences			
Item	**Predicate Devices (K223435)** • **FreeStyle Libre 2 Flash Glucose Monitoring System** • **FreeStyle Libre 3 Continuous Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 2 Flash Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 3 Continuous Glucose Monitoring System**
Contraindications Against MRI/Diathermy/CT	MRI, Diathermy and CT	Diathermy	
Caution and Warning Against X-Rays	Yes	No	
Method to Display Current Glucose Result and Trend Arrow	FSL2 System BLE for glucose data transfer to issue alarms. User-initiated scan via NFC required to display glucose data. FSL3 System Bluetooth Low Energy (BLE). Data automatically transfers to issue alarms and display glucose data without user-initiated scan (streaming data).	Bluetooth Low Energy (BLE). Data automatically transfers to issue alarms and display glucose data without user-initiated scan (streaming data). A user-initiated scan via NFC can also be performed to display real-time glucose data and recent historical data, consistent with the predicate FSL2 App.	Same as predicate FSL3 System
Primary Display Device	FSL2 System FreeStyle Libre 2 App FreeStyle Libre 2 Reader FSL3 System FreeStyle Libre 3 App FreeStyle Libre 3 Reader	FreeStyle Libre App FreeStyle Libre 2 Reader	FreeStyle Libre App FreeStyle Libre 3 Reader

Differences			
Item	**Predicate Devices (K223435)** • **FreeStyle Libre 2 Flash Glucose Monitoring System** • **FreeStyle Libre 3 Continuous Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 2 Flash Glucose Monitoring System**	**Subject Device:** **FreeStyle Libre 3 Continuous Glucose Monitoring System**
App Stopped Alarm	FSL2 System iOS only FSL3 System iOS and Android	Same as Predicate FSL3 System	
App User Interface Navigation	Side panel navigation	Bottom bar navigation menu	
App Alarm Volume Escalation	No App Alarm Volume Escalation	Increases the volume of alarms (High Glucose Alarm, Low Glucose Alarm, Urgent Low Glucose Alarm and Signal Loss Alarm) in custom tone until it reaches a maximum volume, over 30 seconds, equal in volume to that of the predicate device alarms.	

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:

- Compatibility with system-specific sensor.
- Use of NFC interface for starting new sensors.
- Use of BLE interface for wireless communication with the sensor.
- Use of software algorithm for conversion of sensor raw glucose measurements to calculate glucose results.
- Automatic display of glucose results from FSL3 family of sensors without a user-initiated scan.
- Ability to display of glucose results from FSL2 family of sensors after a user-initiated scan via NFC.
- 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.
- App 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 following major technological differences exist between the subject and predicate devices:

- When used with the FSL 2 family of sensors, the subject device FSL App allows automatic display of glucose results without a user-initiated scan. The user may still perform a scan

of sensors of the FSL2 System as an option. The predicate FSL2 App required a user-initiated scan to display glucose results.

- The subject device labeling removes the contraindications against CT scan and MRI. Both subject FSL2 and FSL3 Systems are now labeled MR conditional.

- The subject device labeling removes the caution and warning against X-ray.

- The subject device FSL App includes an "Alarms Escalation" feature for both iOS and Android. The custom tone volume of High Glucose Alarm, Low Glucose Alarm, Urgent Low Glucose Alarm and Signal Loss Alarm increases incrementally over 30 seconds until the volume reaches maximum level. The final volume of the alarm is same as the alarm volume set in the predicate FSL2 App and FSL3 App. The predicate apps do not include this feature.

5.8 Summary of Performance Testing

The following performance characteristics were evaluated to support substantial equivalence:

- 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 "*Content of Premarket Submissions for Device Software Functions"* dated June 14, 2023, and FDA Guidance "*Multiple Function Device Products: Policy and Considerations"*, dated July 29, 2020. 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 FDA guidance document, "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"* dated September 27, 2023. 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.

- Bench Testing – The subject device underwent additional safety and compatibility performance testing for the sensors to support removal of contraindications against X-ray and computerized tomography (CT) scans and the modification of the magnetic resonance imaging (MRI) contraindication to magnetic resonance (MR) conditional. The test results showed all functionality testing acceptance criteria was met. Previous mechanical, electrical, and functional testing established in the predicate device are not affected by the introduction of the FSL App.

The following supportive performance characteristics were established in the predicate device (K223435) and are not affected by the introduction of the FSL App in this 510(k):

- Biocompatibility
- Sterility
- Shelf Life Stability
- Packaging Integrity/Shipping Integrity
- Electrical Safety and Electromagnetic Compatibility
- Clinical Performance
- Human Factors
- Interoperability

5.9 Conclusion

The FreeStyle Libre 3 Continuous Glucose Monitoring Systems and the FreeStyle Libre 2 Flash Glucose Monitoring Systems 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.