March 3, 2023

Abbott Diabetes Care Inc.
Catherine Yang
Regulatory Affairs Manager
1360 South Loop Road
Alameda, California 94502

Re: K222447
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: August 12, 2022
Received: August 15, 2022

Dear Catherine Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-torres -S

Marianela Perez-Torres, Ph.D.
Acting 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)*
K222477

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)*
K222447

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.

Abbott
Diabetes Care

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.

The assigned 510(k) number is: K222447

1.1. Submitter:

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

Contact: Catherine Yang
Title: Manager, Regulatory Affairs
Phone: (510) 206-9452
Fax: (510) 864-4791

Date Prepared: March 1, 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
Regulatory Section(s):	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 3 Continuous Glucose Monitoring System
Common Name:	Integrated Continuous Glucose Monitoring System, Factory Calibrated
Regulatory Section(s):	21 CFR 862.1355
Classification:	Class II
Product Code(s):	QBJ
Review Panel:	Clinical Chemistry

1.3. Predicate Device

Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K210943, cleared on November 22, 2021)

Reference Devices: 1) FreeStyle Libre 3 Continuous Glucose Monitoring System (K213996 and K212132 cleared May 26, 2022)

The reference device is used only to support the substantial equivalence of the FreeStyle Libre 3 subject device to the predicate device. With the exception of the modified Sensor tail, the FreeStyle Libre 3 subject device is physically identical to the reference device and uses the same cybersecurity design and controls. Therefore, testing completed for the reference device in the areas of sterilization, biocompatibility, shelf-life stability, packaging integrity/shipping integrity, mechanical engineering, electrical safety and electromagnetic compatibility, and cybersecurity applies to the FreeStyle Libre 3 subject device.

1.4. Indications for Use

1.4.1. FreeStyle Libre 2 Flash Glucose Monitoring System

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.

1.4.2. FreeStyle Libre 3 Continuous Glucose Monitoring System

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.

1.5. Device Description

The FreeStyle Libre 2 Flash Glucose Monitoring System (with modified Sensor tail), hereinafter also referred to as 'modified FSL2 System' and FreeStyle Libre 3 Continuous Glucose Monitoring System (with modified Sensor tail), hereinafter also referred to as 'modified FSL3 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 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 the Systems. The Systems require a prescription and are intended for home use.

The FreeStyle Libre 2 System consists of the FreeStyle Libre 2 Sensor and either the FreeStyle Libre 2 Reader or the FreeStyle Libre 2 App downloaded to a compatible smartphone as a primary display device. The FreeStyle Libre 3 System consists of the FreeStyle Libre 3 Sensor and the FreeStyle Libre 3 App downloaded to a compatible smartphone as a primary display device.

Both the FreeStyle Libre 2 and FreeStyle Libre 3 Systems are compatible with the Libre Data Sharing API cleared in K223537. 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.

1.5.1. 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 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 and Android)

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

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 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 and the predicate devices are highlighted in the tables below.

1.6.1. FreeStyle Libre 2 Flash Glucose Monitoring System

Similarities		
Item	**Subject Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with modified Sensor tail) (K222447)**	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K210943)**
Intended Use	The System is intended to monitor interstitial fluid glucose concentrations and communicate with digitally connected devices for the purpose of managing a disease or condition related to glycemic control.	Same
Device type	Integrated CGM	Same
Primary display device(s)	FreeStyle Libre 2 Reader or FreeStyle Libre 2 App (iOS or Android)	Same
Compatible operating systems and hardware platform for App	App is compatible with iOS and Apple smartphone; Android operating system 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
Method of Sensor Activation	Near Field Communication (NFC)	Same
Optional Alarms	Glucose Alarms: Low Glucose Alarm, High Glucose Alarm System Alarm: Signal Loss Alarm	Same

Similarities		
Item	**Subject Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with modified Sensor tail) (K222447)**	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K210943)**
	For Low and High Glucose alarms, a user-initiated action is required to see glucose reading.	
Mandatory Alarms	Glucose Alarm: Urgent Low Glucose System Alarm: Replace Sensor, Sensor Ended, 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
Wireless communication protocol	Near Field Communication (NFC): (13.56 MHz RFID) Bluetooth Low Energy (BLE)	Same
BLE Communication Range	20 feet unobstructed	Same
Sensor Glucose Algorithm	ADC Glucose Algorithm established for the predicate device	Same
Glucose reading update interval	Every 1 minute	Same
Trend Graph Glucose History	8 hours, 24 hour graph and other reports can be used to view logged data	Same
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
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. 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
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
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

Differences		
Item	**Subject Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with modified Sensor tail) (K222447)**	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K210943)**
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.	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.
Intended Use Population	Persons with diabetes age 2 and older	Persons with diabetes age 4 and older
Compatibility with connected devices	Compatible with digitally connected devices, including automated insulin dosing systems for therapy decisions	Compatible with digitally connected devices where the user manually controls actions for therapy decisions
Compatible Sensors	FreeStyle Libre 2 Sensor (15 day)	FreeStyle Libre 2 Sensor (14 day)
Sensor Component	Modified Sensor tail	Sensor tail

Differences		
Item	**Subject Device: FreeStyle Libre 2 Flash Glucose Monitoring System (with modified Sensor tail) (K222447)**	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K210943)**
Contraindications	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.	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.
Interfering Substance Labeling	Vitamin C labeled as an interfering substance at doses of more than 1000 mg of vitamin C per day.	Vitamin C labeled as an interfering substance at doses of more than 500 mg of vitamin C per day.
Interoperability	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.	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.

1.6.2. FreeStyle Libre 3 Continuous Glucose Monitoring System

Similarities		
Item	**Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System (with modified Sensor tail) (K222447)**	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K210943)**
Intended Use	The System is intended to monitor interstitial fluid glucose concentrations and communicate with digitally connected devices for the purpose of managing a disease or condition related to glycemic control.	Same
Device type	Integrated CGM	Same
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
Method of Sensor Activation	Near Field Communication (NFC)	Same
Optional Alarms	Glucose Alarms: Low Glucose Alarm, High Glucose Alarm System Alarm: Signal Loss Alarm	Same
Mandatory Alarms	Glucose Alarm: Urgent Low Glucose System Alarm: 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
Wireless communication protocol	Near Field Communication (NFC): (13.56 MHz RFID) Bluetooth Low Energy (BLE)	Same
Sensor Glucose Algorithm	ADC Glucose Algorithm established for the predicate device	Same
Glucose reading update interval	Every 1 minute	Same

Similarities		
Item	**Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System (with modified Sensor tail) (K222447)**	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K210943)**
Glucose History	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
Method of communication and connectivity with cloud-based applications	App 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
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
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

Differences		
Item	**Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System (with modified Sensor tail) (K222447)**	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K210943)**
Indications for Use	The FreeStyle Libre 3 Continuous Glucose Monitoring System is a real time continuous glucose monitoring (CGM) device with alarms capability indicated for the management of diabetes in persons age 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.	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.
Intended Use Population	Persons with diabetes age 2 and older	Persons with diabetes age 4 and older
Compatibility with connected devices	Compatible with digitally connected devices, including automated insulin dosing systems for therapy decisions	Compatible with digitally connected devices where the user manually controls actions for therapy decisions
System Components	On-body Sensor (No Sensor Applicator assembly required by user prior to applying the Sensor) FreeStyle Libre 3 App	On-body Sensor (User assembles Sensor Applicator and Sensor Container prior to applying the Sensor) FreeStyle Libre 2 App FreeStyle Libre 2 Reader
Primary display device(s)	FreeStyle Libre 3 App (iOS or Android)	FreeStyle Libre 2 App (iOS or Android) or FreeStyle Libre 2 Reader

Differences		
Item	**Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System (with modified Sensor tail) (K222447)**	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K210943)**
Compatible Sensors	FreeStyle Libre 3 Sensor (15 day)	FreeStyle Libre 2 Sensor (14 day)
Sensor Component	Modified Sensor tail	Sensor tail
Sensor Dimension	2.9 mm height / 21 mm diameter	5 mm height / 30 mm diameter
Location of glucose algorithm	Sensor	Receiver (Reader or App)
Method of Data Transfer from Sensor	Bluetooth Low Energy (BLE). Data automatically transfers without user-initiated scan (streaming data).	BLE for glucose data transfer to issue alarms. User-initiated scan via NFC required to display glucose data
BLE Communication Range	33 feet unobstructed	20 feet unobstructed
Information provided with glucose alarm	Alarm type, glucose result and trend arrow	Alarm type
Contraindications	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.	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.
Interfering Substance Labeling	Vitamin C labeled as an interfering substance at doses of more than 1000 mg of vitamin C per day.	Vitamin C labeled as an interfering substance at doses of more than 500 mg of vitamin C per day.
Interoperability	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.	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

Differences		
Item	**Subject Device: FreeStyle Libre 3 Continuous Glucose Monitoring System (with modified Sensor tail) (K222447)**	**Predicate Device: FreeStyle Libre 2 Flash Glucose Monitoring System (K210943)**
	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.	• The FreeStyle Libre 2 App communicates through the cloud to another software device.

1.7. Comparison of Technological Characteristics with the Predicate Device

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

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

- Use of NFC interface for starting new Sensors
- Use of BLE interface to issue alarms
- Use of software algorithm for conversion of the raw glucose measurements from the Sensor to calculate glucose results
- 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)

The following technological differences exist between the subject and predicate devices

- Incorporate a modified Sensor tail to reduce vitamin C interference

- Update Sensor Software and interoperability specification provided to authorized partners to allow compatibility with AID systems and extend the Sensor wear duration from 14 days to 15 days
- Update the App and Reader configurations to disable display of vitamin C interference statements
- Additional software component, the 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

1.8. Summary of Performance Testing

The following summary of performance testing support substantial equivalence to the predicate device:

- Software

  Software regression testing was conducted in accordance with established specifications and IEC 62304 and documentation was provided as recommended by FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The test results met acceptance criteria and support that the subject devices are acceptable for their intended use.

- Interoperability

  Approach to interoperability with authorized partners provides appropriate inputs to support expectations, requirements, and interface specifications to interoperable devices, including AID systems.

- Non-clinical Testing

  Non-clinical performance testing was conducted as per internal design control process requirements. The test results met acceptance criteria and support that the subject devices are acceptable for their intended use.

- Clinical Performance

  A clinical study evaluated clinical performance with respect to reference venous plasma sample YSI measurements across the measuring range throughout a 15-day wear duration in adult (18 years and older) and pediatric (2 to 17 years) participants with diabetes. An additional clinical study evaluated the effects of high doses of vitamin C on the performance with respect to reference venous plasma sample YSI measurements. Analysis of the results from the clinical studies show that the subject devices meet the iCGM special controls for clinical performance set forth in 21 CFR 862.1355.

The following supportive performance characteristics were established in the predicate device (K210943) and the reference devices (K213996 and K212132) and are not affected by the introduction of the modified Sensor tail in this 510(k):

- Sterilization
- Biocompatibility
- Shelf Life Stability
- Packaging Integrity/Shipping Integrity
- Mechanical Engineering
- Electrical Safety and Electromagnetic Compatibility
- Human Factors
- Cybersecurity

1.9. Conclusion

The modified FreeStyle Libre 2 Flash Glucose Monitoring System and the modified FreeStyle Libre 3 Continuous Glucose Monitoring System have the same intended use as the predicate device. 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.