510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K233537

B Applicant

Abbott Diabetes Care Inc.

C Proprietary and Established Names

FreeStyle Libre 3 Continuous Glucose Monitoring System; FreeStyle Libre 2 Flash Glucose Monitoring System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QBJ	Class II	21 CFR 862.1355 - Integrated Continuous Glucose Monitoring System	CH - Clinical Chemistry
QLG	Class II	21 CFR 862.1355 - Integrated continuous glucose monitoring system	CH - Clinical Chemistry
NBW	Class II	21 CFR 862.1345 - Glucose test system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Modification to add a new compatible app (FreeStyle Libre App) as an alternate primary display; removal of labeling contraindications against MRI and CT scan, removal of caution and warning against X-ray.

B Measurand:

Glucose in interstitial fluid

C Type of Test:
Quantitative, amperometric assay (Glucose Oxidase)

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
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.

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.

C Contraindications

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

D Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The following special conditions for use statements apply to both the FreeStyle Libre 2 Flash Glucose Monitoring System and the FreeStyle Libre 3 Continuous Glucose Monitoring System:

- Use of the Sensor with devices, apps, and software that are not listed (as compatible) may cause inaccurate glucose readings.

- Do not ignore symptoms that may be due to low or high blood glucose: Use your blood glucose meter to make treatment decisions when your Sensor readings don't match your symptoms or expectations. Get medical attention when appropriate.
- Use your blood glucose meter to make diabetes treatment decisions when your Sensor reading doesn't match how you feel, has no number, or you see the "check blood glucose" symbol during the first 12 hours of wearing a Sensor. You cannot use Sensor values to make treatment decisions during the first 12 hours.
- Disable your phone's automatic operating system (OS) updates. Prior to updating your phone's OS or updating the App, you should check the Phone and OS Compatibility Guide to determine if the App is compatible. The OS Compatibility Guide is available in the App's Help menu and also at www.FreeStyleLibre.com. You should check the OS Compatibility Guide regularly to make sure that your OS and your phone remain compatible with the App.
- After an OS update, open your App and check your device settings to make sure it's working properly. Some OS features may impact your ability to receive alarms or glucose readings. For example, if you use an iPhone Screen Time feature, add the FreeStyle Libre app to the list of Always Allowed apps to ensure that you receive alarms or if you use an Android Phone do not use the Android Digital Wellbeing app.
- Do not force close the App. The App must be running in the background to receive alarms.
- Don't share the App with another person to avoid confusing glucose information.
- Do not use the System in people under the age in the Indications for Use. The System is not cleared for use under this age.
- Do not use the System if you are on dialysis or critically ill. The System hasn't been evaluted in these groups. Sensor readings may be inaccurate.
- Store the Sensor Kit between 36 °F and 82 °F. Storage outside of this range may cause inaccurate Sensor glucose readings. If you think that the temperature may exceed 82 °F (for example, in an un-airconditioned home in summer), you should refrigerate your Sensor Kit. Do not freeze your Sensor Kit.

The following special conditions for use statements apply to the FreeStyle Libre 2 Flash Glucose Monitoring System only:

- Keep your phone within 20 feet of you at all times, with no obstacles between you. The Sensor itself will not issue alarms. If you're out of range, you may not get alarms. If you want to use the App's optional alarms, turn these on.

The following special conditions for use statements apply to the FreeStyle Libre 3 Continuous Glucose Monitoring System only:

- Keep your phone within 33 feet of you at all times, with no obstacles between you. The Sensor itself will not issue alarms. If you're out of range, you may not get alarms. If you want to use the App's optional alarms, turn these on.

E Special Instrument Requirements:

N/A

IV Device/System Characteristics:

A 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.

FreeStyle Libre 3 Continuous Glucose Monitoring System:

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.

FreeStyle Libre 3 Sensor and FreeStyle Libre 3 Plus 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, 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.

FreeStyle Libre App
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.

FreeStyle Libre 2 Continuous Glucose Monitoring System:

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.

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.

B Principle of Operation:

The FreeStyle Libre 2 Flash Glucose Monitoring System and the FreeStyle Libre 3 Continuous Glucose Monitoring System use an electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF). 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.

C Instrument Description Information:

1. Instrument Name:

   FreeStyle Libre 2 Flash Glucose Monitoring System

   FreeStyle Libre 3 Continuous Glucose Monitoring System

2. Specimen Identification:

   N/A

3. Specimen Sampling and Handling:

   N/A

4. Calibration:

   The sensor is factory calibrated and cannot be calibrated by the user.

5. Quality Control:

   N/A

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

V Substantial Equivalence Information:

A Predicate Device Name(s):
FreeStyle Libre 3 Continuous Glucose Monitoring System; FreeStyle Libre 2 Flash Glucose Monitoring System

B Predicate 510(k) Number(s):
K223435

C Comparison with Predicate(s):

Device & Predicate Device(s):	K233537	K223435
Device Trade Name	Freestyle Libre 3 Continuous Glucose Monitoring System; Freestyle Libre 2 Flash Glucose Monitoring System	FreeStyle Libre 3 Continuous Glucose Monitoring System; FreeStyle Libre 2 Flash Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	A continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes. 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.	Same
Intended Use Population	FSL2 Plus and FSL3 Plus Sensor: Persons with diabetes age 2 and older. FSL2 and FSL3 Sensor: Persons with diabetes	Same

	age 4 and older.	
Test Range	40 to 400 mg/dL	Same
General Device Characteristic Differences		
Contraindications Against MRI/Diathermy/CT	Diathermy	MRI, Diathermy, and CT
Caution and Warning Against X-Rays	No	Yes
Method to Display Current Glucose Result and Trend Arrow	FSL2 and FSL3: Bluetooth Low Energy (BLE). Data automatically transfers to issue alarms and display glucose data without user-initiated scan (streaming data).	FSL2: BLE for glucose data transfer to issue alarms. User-initiated scan via NFC required to display glucose data. FSL3: Same
Primary Display Device	• FreeStyle Libre App • FreeStyle Libre 2 or 3 Reader	• FreeStyle Libre 2 App or Reader • FreeStyle Libre 3 App or Reader
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.	No app alarm volume escalation

VI Standards/Guidance Documents Referenced:

- 21 CFR 862.1355 Integrated Continuous Glucose Monitoring System (iCGM) Special Controls
- ISO 14971 Third Edition 2019-12: Medical devices - Application of risk management to medical devices
- IEC 62304 Edition 1.1 2015-06 Consolidated version: Medical device software - Software life cycle processes

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012, and A2:2010/(R)2012 (Consolidated Text): Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD)
- AAMI TIR69:2017/(R2020): Technical Information Report - Risk management of radio-frequency wireless coexistence for medical devices and systems.
- AAMI TIR57:2016: Principles for medical device security - Risk management.
- IEC 60601-1-2 Edition 4.0 2014-02: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ISO 15223-1 Fourth edition 2021-07: Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Previously established in K193371 (FSL2 Sensor), K212132 (FSL3 Sensor), and K222447 (FSL2 and FSL3 Plus Sensors).

2. Linearity:

   See Assay Reportable Range below.

3. Analytical Specificity/Interference:

   Previously established in K193371 (FSL2 Sensor), K212132 (FSL3 Sensor), and K222447 (FSL2 and FSL3 Plus Sensors).

4. Assay Reportable Range:

   Previously established in K193371 (FSL2 Sensor), K212132 (FSL3 Sensor), and K222447 (FSL2 and FSL3 Plus Sensors).

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   The FSL2 sensor storage shelf-life of 9 months at 36 to 82 °F within the humidity range of 10% - 90% was previously established in K222447.

   The FreeStyle Libre 3 sensor has a storage shelf-life of 7 months, as established in K223435. Shelf-life was evaluated at 36° to 82° Fahrenheit within the humidity range of 10% to 90%.

6. Detection Limit:

   Previously established in K193371 (FSL2 Sensor), K212132 (FSL3 Sensor), and K222447 (FSL2 and FSL3 Plus Sensors).

7. Assay Cut-Off:

   Previously established in K193371 (FSL2 Sensor), K212132 (FSL3 Sensor), and K222447 (FSL2 and FSL3 Plus Sensors).

8. Accuracy (Instrument):

   See comparison studies below.

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Previously established in K193371 (FSL2 Sensor), K212132 (FSL3 Sensor), and K222447 (FSL2 and FSL3 Plus Sensors).

2. Matrix Comparison:

   Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   See section A(3), Analytical Specificity/Interference, above.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Previously established in K193371 (FSL2 Sensor), K212132 (FSL3 Sensor), and K222447 (FSL2 and FSL3 Plus Sensors).

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The glucose measurement range of the device is 40 to 400 mg/dL.

F Other Supportive Instrument Performance Characteristics Data:

The following supportive instrument performance characteristics were established in the predicate devices (K223435) unless mentioned otherwise, 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

The following performance characteristics were verified or validated through studies of the subject devices:

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 for the FreeStyle Libre 2 System and the FreeStyle Libre 3 System are acceptable for their intended use.

Cybersecurity
Abbott Diabetes Care (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.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.