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

I Background Information:

A 510(k) Number

K223435

B Applicant

Abbott Diabetes Care, Inc.

C Proprietary and Established Names

FreeStyle Libre 2 Flash Glucose Monitoring System, FreeStyle Libre 3 Continuous 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
NBW	Class II	21 CFR 862.1345 - Glucose test system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Modifications to include the FreeStyle Libre 3 Reader as an alternative primary display for the FreeStyle Libre 3 Continuous Glucose Monitoring System; and separately to introduce the "Silent Mode" feature in the FreeStyle Libre 2 App and the FreeStyle Libre 3 App.

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:
The 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.

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.

C Contraindications

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.

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: If you are experiencing symptoms that are not consistent with your glucose readings, consult your health care professional.
- Use your blood glucose meter to make diabetes treatment decisions when you see the "check blood glucose" symbol during the first 12 hours of wearing a Sensor. In addition, use your blood glucose meter to make diabetes treatment decisions, if your Sensor glucose reading does not match how you feel, or if the reading does not include a number.
- To prevent missed alarms, make sure the Reader has sufficient charge and that sound and/or vibration are turned on.
- Disable your phone's automatic operating system (OS) updates. Prior to updating your phone's OS or updating the App, you should check the Mobile Device and OS Compatibility Guide to determine if the FreeStyle Libre 3 app is compatible with your OS and your phone. The OS Compatibility Guide is available in the Help Section of the App or on www.FreeStyleLibre.com. You should check the OS Compatibility Guide periodically to make sure that your OS and your phone continue to be 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 and the iOS Screen Time feature, add the FreeStyle Libre 3 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. If you force close the App you will not receive alarms. Re-open the App to ensure you will receive alarms.
- If your phone is not configured correctly, the App will be in "Alarms Unavailable" state and you will not be able to check your glucose or receive any alarms, including the Urgent Low Glucose Alarm.
- Do not use the System in people less than 2 years of age. The System is not cleared for use in people under 2 years of age.
- Do not use the System if you are on dialysis or critically ill. The System is not cleared for use in these groups and it is not known how different conditions or medications common to these populations may affect performance of the System.
- Store the Sensor Kit between 36 °F and 82 °F. Storage outside of this range may cause inaccurate Sensor glucose readings. If you suspect 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.
- Store the Reader between -4°F and 140°F. Storage in temperatures outside of this range, such as in a parked car on a hot day, may cause the Reader to not function properly.
- The System is intended for use by a single person. It must not be used by more than one person due to the risk of misinterpreting glucose information.

- The App and Readers do not share data. Before you start a Sensor, you must choose whether to use the Reader or the App with the Sensor. Once you start a Sensor, you cannot switch your device.
- Do NOT place the Reader in water or other liquids as this may cause it to not function properly and may lead to risk of fire or burns.
- Always use the Abbott provided power adapter and yellow USB cable that came with your Reader to minimize the risk of fire or burns. Take care when plugging and unplugging your USB cable. Do not force or bend the end of the USB cable into the Reader's USB port.
- Do NOT expose the USB cable or power adapter to water or other liquids as this may cause them to not function properly and may lead to risk of fire or burns.
- The Reader is for use by a single person. It must not be used on more than one person including other family members due to the risk of spreading infection. All parts of the Reader are considered biohazardous and can potentially transmit infectious diseases, even after performing the cleaning and disinfection procedure.
- The Reader is not intended for use with multiple patients in health care or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogen.

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

- You must scan the Sensor to get your real-time current glucose level as both the Reader and App will not provide this information without a scan.
- For you to receive alarms, they must be on and your Reader should be within 20 feet of you at all times. The transmission range is 20 feet unobstructed. If you are out of range, you may not receive glucose alarms.

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

- For you to receive alarms, your phone should be within 33 feet of you at all times. The transmission range is 33 feet unobstructed. If you are out of range, you may not receive alarms. If you want to receive the App's optional alarms, make sure these are turned on.

E Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

The subject devices are the FreeStyle Libre 2 (FSL2) Flash Glucose Monitoring System and the FreeStyle Libre 3 (FSL3) Continuous Glucose Monitoring System. The FSL3 Continuous Glucose Monitoring System now includes the FSL3 Reader as an alternate primary display device. Separately, the FSL2 App and the FSL3 App will be updated to include a “Silent Mode”

alarm feature that, when enabled, allows the user to silence the Urgent Low Glucose Alarm, Low Glucose Alarm, High Glucose Alarm and Signal Loss Alarm for a set period of up to 6 hours. The subject FSL2 and FSL3 Systems use the same sensor tail as in the predicate.

FreeStyle Libre 2 Flash Glucose Monitoring System

The FreeStyle Libre 2 (FSL2) Flash Glucose Monitoring System is an integrated continuous glucose monitoring (iCGM) system that performs continuous glucose measurements every minute to provide glucose levels, trends, and real-time alarms capability to aid in the management of diabetes. The FSL2 System requires a prescription, is intended for home use, and consists of the following components:

FreeStyle Libre 2 Sensor

- The Sensor is single use, disposable, and powered by a silver oxide battery. 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 uses near field communication (NFC) to start new Sensors and to scan Sensors to display and record data. The Reader uses Bluetooth low energy (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)

- When downloaded to a compatible smartphone, the FreeStyle Libre 2 App uses NFC communication to start new Sensors and to scan Sensors to display and record data and uses BLE communication to issue alarms. Silent Mode, when enabled, will silence all glucose and signal loss alarms for a set period. 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.

FreeStyle Libre 3 Continuous Glucose Monitoring System

The FreeStyle Libre 3 (FSL3) Continuous Glucose Monitoring System with Reader is an integrated continuous glucose monitoring (iCGM) system that performs continuous glucose measurements every minute to provide glucose levels, trends, and real-time alarms capability to aid in the management of diabetes. The FSL3 System requires a prescription, is intended for home use, and consists of the following components:

FreeStyle Libre 3 Sensor

- The Sensor is single use, disposable, and powered by a silver oxide battery. 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 Reader

- The Reader is a small handheld device that uses near field communication (NFC) to start new Sensors. The Reader uses Bluetooth low energy (BLE) communication to display glucose data and issue alarms based on the measurements calculated by the Sensor. 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 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. Silent Mode, when enabled, will silence all glucose and signal loss alarms for a set period. The FreeStyle Libre 3 App allows connectivity with cloud-based applications. The FreeStyle Libre 3 App is an alternative primary display for the System and does not interact with the Reader. 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.

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 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 ISF. The system converts the electrical current signal to a glucose value (in mg/dL) accompanied by trend arrow for display to the user on a display device.

C Instrument Description Information:

1. Instrument Name:

   FreeStyle Libre 2 Flash Glucose Monitoring System

   FreeStyle Libre 3 Continuous Glucose Monitoring System

2. Specimen Identification:

   Not applicable.

3. Specimen Sampling and Handling:

   Not applicable.

4. Calibration:

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

5. Quality Control:

   Not applicable.

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 2 Flash Glucose Monitoring System

Freestyle Libre 3 Continuous Glucose Monitoring System

B Predicate 510(k) Number(s):

K222447

C Comparison with Predicate(s):

Device & Predicate Device(s):	K223435	K222447
Device Trade Name	FreeStyle Libre 2 Flash Glucose Monitoring System FreeStyle Libre 3 Continuous Glucose Monitoring System	FreeStyle Libre 2 Flash Glucose Monitoring System FreeStyle Libre 3 Continuous Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use	The Systems are continuous glucose monitoring devices with real time alarms capability indicated for the management of diabetes in persons age 2 and older.	Same

Device & Predicate Device(s):	K223435	K222447
General Device Characteristic Differences		
Primary Display Device	FreeStyle Libre 2 Reader FreeStyle Libre 2 App FreeStyle Libre 3 Reader FreeStyle Libre 3 App	FreeStyle Libre 2 Reader FreeStyle Libre 2 App FreeStyle Libre 3 App
Silent Mode	Yes	No

VI Standards/Guidance Documents Referenced:

- 21 CFR 862.1355 integrated continuous glucose monitoring system (iCGM) special controls
- ISO 14971: 2019 - Medical Devices – Application of risk management to medical devices
- ANSI AAMI 60601-1:2005/(R)2012 and A1:2012 - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6 - General Requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-1-11 - General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in home healthcare environment
- IEC 60601-1-2:2014-02 Edition 4.0 - General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- AAMI TIR69: 2017 - Risk Management of Radio-frequency Wireless Coexistence for Medical Devices and Systems
- ANSI C63.27-2017 - American National Standard for Evaluation of Wireless Coexistence
- ANSI AAMI IEC 62366-1:2015 - Medical devices - Application of usability engineering to medical devices
- AAMI / ANSI HE75: 2009/(R)2018 - Human Factors Engineering - Design of Medical Devices
- AAMI TIR57: 2016 - Principles for medical device security – Risk management
- IEC 62304: 2006/A1:2016 - Medical device software – Software life cycle processes
- AAMI / ANSI / ISO 10993-1: 2018 - Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management process
- ISO 15223-1:2021 - Medical device – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General Requirements
- FDA Guidance document Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016)
- FDA Guidance document Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)

- FDA Guidance document Electromagnetic Compatibility (EMC) of Medical Devices (June 6, 2022)
- FDA Guidance document Radio Frequency Wireless Technology in Medical Devices (August 14, 2013)
- FDA Guidance document Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (October 2, 2014)
- FDA Guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (September 4, 2020)
- FDA Guidance document Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices (September 6, 2017)
- FDA Guidance document Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions (December 20, 2019)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

The subject FreeStyle Libre 2 System and FreeStyle Libre 3 System are physically identical to the predicate FreeStyle Libre 2 System and predicate FreeStyle Libre 3 System except for the inclusion of the FreeStyle Libre 3 Reader. Therefore, the pivotal clinical studies for the predicate devices (K222447) are leveraged for the subject devices.

1. Precision/Reproducibility:

   Previously established in K222447.

2. Linearity:

   See Assay Reportable Range below.

3. Analytical Specificity/Interference:

   Previously established in K222447.

4. Assay Reportable Range:

   Previously established in K222447.

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

   The storage shelf-life of 9 months at 36 to 82 °F within the humidity range of 10 % - 90 % previously established for the predicate FreeStyle Libre 2 Sensor in K222447 is applicable to the FreeStyle Libre 2 Sensor.

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

6. Detection Limit:

   Previously established in K222447.

7. Assay Cut-Off:

   See Assay Reportable Range and Detection Limit above.

8. Accuracy (Instrument):

   Not applicable.

9. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable. Accuracy is determined by comparing device values to an FDA cleared laboratory grade glucose measurement method.

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 K222447.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

F Other Supportive Instrument Performance Characteristics Data:

The following supportive instrument performance characteristics were established in the predicate devices (K222447) unless mentioned otherwise, and are not affected by the addition of the FreeStyle Libre 3 Reader and "Silent Mode" in the current 510(k):

- Sterilization
- Biocompatibility
- Environmental testing
- Packaging integrity/shipping integrity
- Mechanical engineering
- Interoperability

The following performance characteristics were verified or validated through studies of the current design:

Human Factors

Human factors and usability testing of the FreeStyle Libre 2 System with FSL2 Reader in K193371 was leveraged to support the FreeStyle Libre 3 System with FSL3 Reader.

Human factors and usability testing of the "Silent Mode" alarm feature was conducted to determine whether the user interface design and labeling would impact the performance of the devices. Human factors testing was conducted in accordance with:

- Applying Human Factors and Usability Engineering to Medical Devices, Guidance to FDA Staff and Industry, February 3, 2016
- ANSI/AAMI/IEC 62366: Medical devices - Application of Usability Engineering to Medical Devices
- IEC 60601-1-6: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Specific use scenarios and tasks the user would have to carry out correctly in order to use the device safely were identified. An analysis of hazards and risks was conducted on the FreeStyle Libre 2 App to determine safety risks associated with use of the system. All critical tasks for which a use error could lead to high severity harm were evaluated with validation testing. As the tasks for "Silent Mode" on the FreeStyle Libre 2 App are the same as on the FreeStyle Libre 3 App, the human factors testing is leveraged for the FreeStyle Libre 3 App.

Software Verification and Validation

Software verification and validation testing was conducted to confirm that the software used in the FreeStyle Libre 2 System and the FreeStyle Libre 3 System performed in accordance with established specifications, IEC 62304 and FDA Guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," May 11, 2005. Evaluation activities included unit, system integration (SIT), and system level testing which verified functionality of the device against established software requirements. Results of the software 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 in accordance with the FDA Guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" (October 2, 2014). 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.

In addition, ADC has controls and processes in place to ensure continued support for keeping the device secure and to ensure that the device firmware, software and components are malware free. Additional controls are also in place in manufacturing through distribution to ensure that the medical device firmware and software are malware free from point of origin to the hands of the end user.

Wireless Coexistence
The FreeStyle Libre 3 System (with the FSL3 Reader) underwent coexistence testing in the presence of common RF interfering devices that are likely to be encountered by users in a home environment. Wireless coexistence testing was performed to confirm that the FSL3 Sensor with the FSL3 Reader remains functional and perform within acceptable limits while in the presence of common radiating electronic devices in accordance with FDA Guidance "Radio Frequency Wireless Technology in Medical Devices." A representative set of devices known to operate in the same frequency band (2.4 GHz) was selected and tested following methods consistent with AAMI TIR69 and ANSI C63.27. The test results showed that the FreeStyle Libre 3 System (with the FSL3 Reader) could tolerate interference generated by these RF interfering devices and still meet the target performance criteria.

Electrical Safety and Electromagnetic Compatibility
Electrical safety data was leveraged from K212132 and K193371 as the Sensor electronics have not changed in the FSL2 and FSL3 Sensors, the FSL2 Reader has not changed, the hardware for the FSL3 Reader is identical to the predicate FSL2 Reader, and the App only interacts with the Sensor via NFC and BLE radios on the compatible mobile phone (which independently have been tested to be compliant with applicable electrical safety standards, as previously established in the App configurations of the cleared FSL2 and FSL3 systems).

Electromagnetic Compatibility (EMC) testing (radiated emissions, radiated immunity and magnetic field immunity) was leveraged from K193371 for the FreeStyle Libre 3 System (with the FSL3 Reader) as the FSL3 Reader hardware is identical to the predicate FSL2 Reader. Previous electrostatic discharge (ESD) and other device EMC testing is leveraged from K212132 and K213996.

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.