510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K201761

B Applicant

Abbott Diabetes Care Inc.

C Proprietary and Established Names

FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
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 an existing device to use a mobile app as an alternate primary display.

B 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 (with FreeStyle Libre 2 App) 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The System must not be used with automated insulin dosing (AID) systems, including closed loop, hybrid closed loop, and insulin suspend systems.

Taking ascorbic Acid (Vitamin C) supplements while wearing the Sensor may falsely raise Sensor glucose readings. Inaccurate sensor readings due to ascorbic acid interference may be clinical significant and result in harm if relied on to make treatement decisions. Taking more than 500 mg of ascorbic acid per day may affect the Sensor readings which could cause you to miss a severe low glucose event.

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.

Do not use this system if you are pregnant, 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.

Do not ignore symptoms that may be due to low or high blood glucose: if you are experiencing symptoms that are not consistent with the glucose readings, consult your health care professional.

Do not use the System in people less than 4 years of age.

Use your blood glucose meter to make diabetes treatment decisions when you see the "check blood glucose" symbol during the first 12 hours or 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.

Wash application site on the back of your upper arm using a plain soap, dry, and then clean with an alcohol wipe. This will help remove any oily residue that may prevent the sensor from sticking properly. Allow site to air dry before proceeding. Carefully preparing the site according to these instructions will help the Sensor stay on your body for the full 14-day wear period and help prevent it from falling off early.

Store the Sensor Kit between 36°F and 82°F. If you suspect that the temperature may exceeed 82°F (e.g., an un-airconditioned home in the summer), you should refridgerate your Sensor Kit. Do not freeze your Sensor Kit.

You must scan the Sensor to get your real-time current glucose level as the Reader will not provide this information without a scan.

The Readers's built-in meter is not for use on people who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.

The Reader's built-in meter is not for use on neonates, in critically-ill patients, or for diagnosis or screening of diabetes.

The Reader's built-in meter is for use by a single person.

Use of the Reader's built-in meter on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

Use of the Sensor with devices, apps, and software that are not listed by the manufacturer as compatible with the System may cause inaccuracte glucose readings.

If a Sensor breaks inside a user's body, they should call their health care professional.

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.

To prevent missed alarms, make sure the Reader has sufficient charge and that sound and/or vibration are turned on.

Alarms you receive do not include your glucose reading so you must scan your Sensor to check your glucose.

For you to receive alarms, your phone 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 alarms. If you want to receive the App's optional alarms, make sure these are turned on.

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.

Alarms you receive do not include your glucose reading so you must scan your Sensor to check your glucose.

The App will ask for phone permissions which are needed to receive alarms. Allow these permissions when requested.

Check to make sure that you have the correct phone settings and permissions enabled. If your phone is not configured properly, you will not be able to use the App, so you will not receive alarms or be able to check your glucose.

If you adjust the phone ringer volume to silent or use the phone Do Not Disturb setting, keep 'Override Do Not Disturb' setting in the App ON for Low Glucose, High Glucose, and Signal Loss alarms to ensure you receive audible alarms.

You should disconnect headphones or speakers from your phone when you are not using them as you may not hear audio for alarms. If using headphones, keep them in your ears.If you are using peripheral devices connected to your phone, such as wireless headphones or a smartwatch, you may receive alarms on only one device or peripheral, not all.

Some operating system features may impact your ability to receive alarms. For example, if you use the iOS Screen Time feature, add FreeStyle Libre 2 to the list of Always Allowed apps to ensure that you receive alarms.

Keep your phone well charged and turned on.

If you are using FreeStyle Libre 2 App, you must have access to a blood glucose monitoring system as the App does not provide one.

FreeStyle Libre 2 app installed on a smartphone 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 uses all available glucose data to give you readings so you should scan your Sensor at least once every 8 hours for the most accurate performance. Scanning less frequently may result in decreased performance.

IV Device/System Characteristics:

A Device Description:

The subject device is the FreeStyle Libre 2 ("FSL2") Flash Glucose Monitoring System (with FreeStyle Libre 2 App) and is modified from the previously cleared system in K193371. This submission adds the FreeStyle Libre 2 App ('FSL2 App' or 'App'), which is an alternative primary reader option for the FSL2 System. No changes are proposed to the previously cleared

sensor or reader. When used with the FSL2 Sensor (or "Patch") cleared under K193371, the proposed mobile app allows the user to:

- activate FSL2 Sensors,
- view important safety information, alarm status, and measured interstitial fluid (ISF) glucose levels, and
- connect with cloud-based applications to store and share data (e.g., LibreView).

The device is intended for use in people with diabetes mellitus, age 4 and older. The user downloads the app from the Apple App Store for iOS.

Principle of Operation

Upon user-initiated scan enabled by near-field communication (NFC) technology, the FSL2 App can wirelessly query glucose data from the sensor by bringing a compatible smartphone in proximity of the sensor. An app can only be paired with one sensor. The FSL2 system uses Bluetooth Low Energy (BLE) to transfer glucose data each minute from the Sensor, which allows for alarms to be presented to the user.

Upon scanning, glucose values are calculated by the App using the same algorithm as the previously cleared Reader (K193371). The scan results include glucose measurements, trend information, historic 8-hr glucose results, and any applicable glucose messages. Glucose information is accompanied by background colors, which indicates how a glucose measurement compares with a user-specified range. Before obtaining glucose measurements, a 1-hour warm-up period is required after sensor activation. A check blood glucose icon appears notifying the user that a blood glucose test must be used to confirm sensor readings during the first 12 hours of wear before making treatment decisions. The app supports manual entry of blood glucose values as well as event logging. The user may generate and share a range of report types, stratified by 7, 14, 30, or 90 days. The App stores up to 90 days of data.

System Components and Features

Alarms: The App is designed to issue glucose alarms that notify the user to perform a scan when glucose has passed a glucose threshold. The FSL2 App can issue the following glucose and system alarms:

- Optional Alarms: Low Glucose Alarm, High Glucose Alarm, Signal Loss Alarm
    - For the optional alarms above, the Override Do Not Disturb (DND) setting is turned on by default; therefore, the user receives these alarms regardless of the phone's sound, vibe or DND settings. If the user wishes to have the optional alarms follow the phone's sound and vibe settings, the user must turn off Override DND from the App.

- Mandatory Alarms: Urgent Low Alarm, Sensor Termination Alarms, App Stopped (Force Closed)
    - These alarms cannot be turned off or modified and will always sound regardless of the phone's sound and vibe or DND settings.

Hardware / Software compatibility: The FreeStyle Libre 2 App is intended for use with NFC and BLE-enabled smartphones running compatible iOS operating systems. The FSL2 App is only compatible with FSL2 sensors.

Secondary Viewers: LibreView and LibreLinkUp (LLU) provide a cloud-based repository for glucose measurement data and mobile app that allows caregivers to receive and view glucose data (including glucose alarms) from users who use the FSL2 App with their sensor. Secondary viewers are not intended to be used for immediate clinical decision making.

B Instrument Description Information:

1. Instrument Name:

   FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App)

2. Specimen Identification:

   N/A

3. Specimen Sampling and Handling:

   N/A

4. Calibration:

   The sensor is factory calibrated and does not require calibration from the user/operator.

5. Quality Control:

   N/A

V Substantial Equivalence Information:

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

B Predicate 510(k) Number(s):
K193371

C Comparison with Predicate(s):

Device & Predicate Device(s):	K201761 (subject device)	K193371 (predicate device)
Device Trade Name	FreeStyle Libre 2 Flash Glucose Monitoring System (with FSL2 App)	FreeStyle Libre 2 Flash Glucose Monitoring System
Manufacturer	Abbott Diabetes Care	Abbott Diabetes Care

General Device Characteristic Similarities		
Intended Use/Indications For Use	The FreeStyle Libre 2 Flash Glucose Monitoring System (with FSL2 App) 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.	SAME
Device Type	Integrated CGM	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	RFID communication	SAME

Method of Data Transfer from Sensor	RFID – upon user-initiated scan BLE – for glucose data to support glucose alarms	SAME
BLE Communication Range	20 feet unobstructed	SAME
Sensor Glucose Algorithm	The app uses the same algorithm as the FreeStyle Libre 2 Reader	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
Optional Alarms	Low Glucose Alarm, High Glucose Alarm, Signal Loss Alarm For Low and High Glucose alarms, a user-initiated action is required to see glucose reading	SAME
General Device Characteristic Differences		
Primary display device(s)	FreeStyle Libre 2 Reader or FreeStyle Libre 2 App	FreeStyle Libre 2 Reader
Mandatory alarms	The App includes mandatory alarms for Urgent Low Glucose, Replace Sensor, Sensor Ended, App Stopped These alarms are mandatory (set to 'On') and cannot be modified by the user. For Urgent Low Glucose alarm, a user-initiated action is required to see glucose reading	Not applicable.
Blood glucose meter	While using the App, user must have access to a blood glucose monitoring system as the App does not provide one.	An integrated BGM is provided with the Reader. The FreeStyle Libre 2 Reader has a built-in blood glucose meter that is designed to be used only with FreeStyle Precision Neo blood glucose test strips and MediSense Glucose and Ketone Control

		Solution.
Method of communication and connectivity with cloud-based applications	App only: can communicate wirelessly to LibreView. Through LibreView, can communicate to LibreLinkUp App	The Reader can communicate and connect with LibreView through the USB port connection with the desktop computer. The Reader does not have wireless capabilities to interface with LibreLinkUp App.
Compatible operating systems and hardware platform	Compatible with Apple iOS	The Reader is microcontroller-based electronic device manufactured with various electronics and plastic parts. The Reader does not require iOS operating system function.

VI Standards/Guidance Documents Referenced:

- 21 CFR 862.1355 (integrated continuous glucose monitoring system (iCGM)) special controls
- ISO14971-"Medical Devices-Application of Risk Management to Medical Devices"
- AAMI/IEC 62366-1-"Medical Devices-Application of Usability Engineering to Medical Devices"
- AAMI/ANSI HE75-"Human Factors Engineering -Design of Medical Devices"
- IEC 60601-1-6: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-"Medical Electrical Equipment -Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-11-"Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment"
- IEC 60601-1-2-"Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests"
- ANSI C63.27-2017- "American National Standard for Evaluation of Wireless Coexistence"
- AAMI TIR69-"Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems"
- EN 62304-"Medical Device Software-Software Life Cycle Processes
- AAMI/ANSI/ISO 10993-1-" Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing within a Risk Management Process"

- ISO 11137-1-"Sterilization of Health Care Products-Radiation Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices"
- ISO11137-2-"Sterilization of Health Care Products-Radiation Part 2: Establishing of the Sterilization Dose"
- ISO 11607-1-"Packaging for Terminally Sterilized Medical Devices-Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems"
- ISO 11607-2-"Packaging for Terminally Sterilized Medical Devices-Part 2: Validation Requirements for Forming, Sealing and Assembly Processes"
- ASTM D4169-"Standard Practice for Performance Testing of Shipping Containers and System"
- ISO 15223-1-"Medical Device-Symbols to be used with Medical Device Labels, Labeling and Information to be Supplied-Part 1: General Requirements
- IEC 60417-"DB Graphical Symbols for Use on Equipment"
- FAA AC no. 91.21-1C-"Use of Portable Electronic Devices Aboard Aircraft"
- FCC Title 47: Part 15-"Radio Frequency Devices, Conducted Limits, Section 15.225 and Section 15.247"
- AAMI TIR57: 2016- "Principles for medical device security – Risk management"

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Previously established in k193371.

2. Linearity:

   The reportable range for the System is 40 to 400 mg/dL.

3. Analytical Specificity/Interference:

   Previously established in k193371.

4. Accuracy (Instrument):

   Not applicable.

5. Carry-Over:

   Not applicable.

B Other Supportive Instrument Performance Characteristics Data:

The following supportive instrument performance characteristics were established in the predicate for the FSL2 Continuous Glucose Monitoring System (K193371), and are not affected by the addition of the App in the current 510(k):

- Sterilization
- Biocompatibility
- Mechanical Engineering
- Environmental Testing
- Shelf-Life Stability
- Packaging Integrity/Shipping Integrity
- Interoperability

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

- Software
  Software verification and validation testing was conducted to confirm that the software used in the FreeStyle Libre 2 System performed in accordance with established specifications, EN 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 FreeStyle Libre 2 met the acceptance criteria and therefore supports that the System's iOS App software is acceptable for its intended use.

- Human Factors
  Human factors and usability testing of the FreeStyle Libre 2 System (with FreeStyle Libre 2 App) was conducted to determine whether the user interface design and labeling would impact the performance of the device. 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 System 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.

- Cybersecurity
  ADC has provided cybersecurity risk management documentation for the FreeStyle Libre 2 System (with FreeStyle Libre 2 App) that includes analysis of confidentiality, integrity,

and availability for data, information and software related to the System. 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. 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 2 System (with FreeStyle Libre 2 App) underwent coexistence testing in the presence of common RF interfering devices that are likely to be encountered by users in a home environment. A representative set of devices known to operate in the same frequency band (2.4 GHz) was selected. The test results showed that the FreeStyle Libre 2 System could tolerate interference generated by these RF interfering devices and still meet the target performance criteria.

- Electrical Safety and Electromagnetic Compatibility
  Electromagnetic Compatibility (EMC) testing was performed to verify that the system was able to withstand electromagnetic interference in compliance with IEC 60601-1-2:2014. Representing a worst-case test scenario, EMC testing from K202145, was used to establish the safety performance of the FreeStyle Libre 2 System (with FreeStyle Libre 2 App).

  A risk management process was used to evaluate the basic safety and essential performance of the FreeStyle Libre 2 System (with FreeStyle Libre 2 App) per IEC 60601-1:2005(r)2012.

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.