510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K223537

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
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:

The submission adds application programming interfaces (APIs) to the FreeStyle Libre 2 and FreeStyle Libre 3 iCGM systems to facilitate users sharing glucose data with authorized client software for specific and permitted use cases.

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 Indications for Use statement for the FreeStyle Libre 2 Flash Glucose Monitoring System previously included a statement regarding sensor compatibility. This statement has been removed in the current submission. This modification does not change the cleared indications for use or intended use of the device system. Information on sensor compatibility can be found in device labeling.

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.

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.

C Contraindications

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.

D Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The following special conditions for use statements apply to the Libre Data Sharing API:

- Use of the Libre Data Sharing API and the CGM information it transmits is limited by the indications for use of the iCGM systems with which it is used.

The following special conditions for use statements apply to the FreeStyle Libre 2 (FSL2) device:

- 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.
- 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 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.
- 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 wear duration specified by your Sensor insert and help prevent it from falling off early.
- 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 (e.g., an un-airconditioned home in the summer), you should refrigerate your Sensor Kit. Do not freeze your Sensor Kit.
- The Reader'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 (as compatible) may cause inaccurate glucose readings.
- If a Sensor breaks inside a user's body, call your health care professional.
- Alarms you receive do not include your glucose reading. You must scan the Sensor to get your real-time current glucose level as the Reader and App will not provide this information without a scan.
- For you to receive alarms, they must be on in your Reader. If you want to receive the App's optional alarms, make sure these are turned on. The Reader or 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 glucose alarms.
- To prevent missed alarms, make sure the Reader has sufficient charge and that sound and/or vibration are turned on.
- 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.
- Do not force close the App (iOS). 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 you adjust the phone ringer volume (iPhone) or Media volume (Android) 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 an iPhone and the iOS Screen Time feature, add FreeStyle Libre 2 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.
- 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 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 following special conditions for use statements apply to the FreeStyle Libre 3 (FSL3) (FSL3) device:

- Do not use the System in people less than 4 years of age. The System is not cleared for use in people under 4 years of age.
- Do not use the 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.

- The FreeStyle Libre 3 app installed on a phone 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.
- Performance of the System when used with other implanted medical devices, such as pacemakers, has not been evaluated.
- Taking ascorbic acid (vitamin C) supplements while wearing the Sensor may falsely raise Sensor glucose readings. 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. Ascorbic acid can be found in supplements including multivitamins. Some supplements, including cold remedies such as Airborne® and Emergen-C®, may contain high doses of 1000 mg of ascorbic acid and should not be taken while using the Sensor. See your health care professional to understand how long ascorbic acid is active in your body.
- 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.
- Use your blood glucose meter to make diabetes treatment decisions when you see the symbol during the first 12 hours of wearing a Sensor, if your Sensor glucose reading does not match how you feel or if the reading does not include a number.
- For you to receive alarms, they must be on and your device 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 suspect that the temperature may exceed 82°F (for example, in an unairconditioned home in summer), you should refrigerate your Sensor Kit. Do not freeze your Sensor Kit.
- 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.

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. Both systems utilize the FreeStyle Libre App with different app versions for the FSL2 and FSL3, and both app versions are available on Apple and Android mobile phone operating systems. The device descriptions of the FSL2 and FSL3 systems are unchanged from K210943 and K213996, respectively.
As part of the current 510(k) the subject devices are receiving additional functionality called the "Libre Data Sharing API."

The Libre Data Sharing API is a cloud-based application programming interface (API) that is intended to enable communication of glucose data, including alarms, through the cloud from an FDA cleared Abbott iCGM system, consisting of an on-body sensor and a primary display device, to an authorized third-party organization ('client') software on digitally connected devices. The data transmitted by the API to an authorized client software can be used for specific and permitted use cases, including non-medical device applications, medical device data analysis, CGM secondary display alarm, active patient monitoring, and treatment decisions. Use of the Libre Data Sharing API and the CGM information it transmits is limited by the indications for use of the iCGM systems with which it is used.

The Libre Data Sharing API does not have any command or control over the client software, nor does it allow for the client software to have any command or control over the connected iCGM system. Additionally, glucose data and alarms from the connected iCGM system are not modified or manipulated by the Libre Data Sharing API through its transmission to the authorized client software. The display device of the connected Abbott iCGM system, which directly receives the data from the sensor, continues to serve as a primary display device for the glucose data and alarms. As part of this 510(k) there are no modifications to the sensors, transmitters, or user interfaces of the FSL2 or FSL3 systems.

As a component of iCGM systems, the Libre Data Sharing API is subject to the applicable special controls defined in 21 CFR 862.1355. FDA determined that the technical design of the Libre Data Sharing API and the verification and validation testing provided in the current 510(k) are adequate to meet the iCGM special controls. In addition to these regulatory controls, Abbott Diabetes Care elected to use a "whitelist" approach to control access to the API, such that access by 3rd party developers will require prior authorization from Abbott Diabetes Care.

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:

   Unchanged from K210943 for the FSL2 and K213996 for the FSL3.

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 (with FreeStyle Libre 2 App)

FreeStyle Libre 3 Continuous Glucose Monitoring System

B Predicate 510(k) Number(s):

K210943, K213996

C Comparison with Predicate(s):

Device & Predicate Device(s):	K223537	K210943
Device Trade Name	FreeStyle Libre 2 Flash Glucose Monitoring System	FreeStyle Libre 2 Flash Glucose Monitoring System (with FreeStyle Libre 2 App)
General Device Characteristic Similarities		
Intended Use/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 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	Same

	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.	
General Device Characteristic Differences		
Application Programming Interfaces (APIs)	Enables users to share their glucose data with authorized client software. Can communicate iCGM data wirelessly and securely to and from digitally connected devices (client software) through a cloud-based communication method.	No API functionality

Device & Predicate Device(s):	K223537	K213996
Device Trade Name	FreeStyle Libre 3 Continuous Glucose Monitoring System	FreeStyle Libre 3 Continuous Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/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 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	Same

	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.	
General Device Characteristic Differences		
Application Programming Interfaces (APIs)	Enables users to share their glucose data with authorized client software. Can communicate iCGM data wirelessly and securely to and from digitally connected devices (client software) through a cloud-based communication method.	No API functionality

VI Standards/Guidance Documents Referenced:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] (July 28, 2014)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (October 2, 2014)
- Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices (September 6, 2017)
- Format for Traditional and Abbreviated 510(k)s (September 13, 2019)
- Multi-Function Device Products: Policy and Considerations (July 29, 2020)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Performance established in K210943 for the FSL2 and K213996 for the FSL3.

2. Linearity:

   Previously established in K210943 for the FSL2 and K213996 for the FSL3.

3. Analytical Specificity/Interference:

   Previously established in K210943 for the FSL2 and K213996 for the FSL3.

4. Accuracy (Instrument):

   Previously established in K210943 for the FSL2 and K213996 for the FSL3.

5. Carry-Over:

   Not Applicable

B Other Supportive Instrument Performance Characteristics Data:

The following supportive instrument performance characteristics were established in prior 510(k) clearances for the FSL2 and FSL3 system, and are not affected by the addition of the Libre Data Sharing API:

- Human Factors
- Biocompatibility
- Sterilization
- Shelf Life and Stability
- Packaging Integrity/Shipping Integrity
- Electromagnetic Compatibility
- Electrical Safety
- Environmental Testing
- Blood Glucose Meter Functionality
- Interoperability

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

- Software
- Cybersecurity

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.