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

I Background Information:

A 510(k) Number

K193371

B Applicant

Abbott Diabetes Care Inc.

C Proprietary and Established Names

FreeStyle Libre 2 Flash 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:

New device

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 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 interfernce may be clinically significant and result in harm if relied on to make treatment 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 Sysetm 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 additoin, 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 clea with an alcohol wipe. This will hep 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.

Take standard precautions for transmission of blood borne pathogens to avoid contamination.

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 healthcare professional.

D Special Instrument Requirements:
N/A

IV Device/System Characteristics:

A Device Description:

The FreeStyle Libre 2 Flash Glucose Monitoring System (hereon referred to as the ‘FreeStyle Libre 2 System or ‘System’) is an integrated continuous glucose monitoring system (iCGM) that provides continuous glucose measurements every minute to provide glucose levels, trends and alerts. The FreeStyle Libre 2 System consist of two primary components: a sensor which transmits via Bluetooth Low Energy (BLE) and a BLE enabled display device (Reader). User-initiated scanning provides the user with current glucose measurements (glucose values) accompanied by trend information (glucose arrows) and historical glucose information (glucose graph). The user may determine their treatment based on the glucose values provided by the

System. The Reader does not provide glucose values, arrows, or graph information to users in the absence of a user-initiated action (a sensor scan). The Reader only monitors glucose values in real-time to provide alerts and alarms which, when enabled, warn the user of Low Glucose, High Glucose or Signal Loss and prompt the user to scan the Sensor.

FreeStyle Libre 2 Sensor

- The Sensor is single use and disposable. The Sensor is provided as two secondary components, Sensor Applicator and Sensor Pack (sterile device) which are used to assemble and apply the Sensor to the back of the user's arm. 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 14 days.

FreeStyle Libre 2 Reader

- The Reader is a small handheld device, which uses RFID communication to start new sensors and to scan sensors to display and record data. It also uses BLE communication to issue alarms that notify the user to perform a user-initiated scan when glucose has passed a high or low glucose threshold. The Reader also has a built-in strip port with blood glucose meter functionality (that is intended to work with the FreeStyle Precision Neo Blood Glucose test strips, cleared under K171941), and a user interface which includes event logging features. Modifications to the blood glucose meter functionality include the addition of a BLE chip. (The modifications would not impact the blood glucose meter performance, therefore new performance data was not evaluated in this submission.)

The FreeStyle Libre 2 System is an interoperable connected device that can communicate glucose readings and other information wirelessly and securely to and from interoperable electronic interfaces. The System is intended to be used where the user utilizes CGM information to manually control actions for therapy decisions. The device is also designed, and has been validated, to be able to provide real-time glucose information to other digitally connected devices that are authorized to be used in that manner. The System must not be used with automated insulin dosing (AID) systems, including full closed loop, hybrid closed loop, and insulin suspend (e.g., threshold suspend and predictive low glucose suspend) systems.

B Principle of Operation:

The FreeStyle Libre 2 Flash Glucose Monitoring System uses an electrochemical sensor to monitor glucose levels in the interstitial fluid (ISF). The sensor incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the interstitial fluid. The FreeStyle Libre 2 System converts the electrical current signal to a glucose value (in mg/dL) for display on the handheld Reader.

C Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☒	☐
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:
   FreeStyle Libre 2 Flash Glucose Monitoring System

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):
Dexcom G6 Continuous Glucose Monitoring System

B Predicate 510(k) Number(s):
DEN170088

C Comparison with Predicate(s):

Device & Predicate Device(s):	K193371	DEN170088
Device Trade Name	FreeStyle Libre 2 Flash Glucose Monitoring System	Dexcom G6 Continuous Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose	The Dexcom G6 Continuous Glucose Monitoring System (Dexcom G6 System) is

	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.	a real time, continuous glucose monitoring device indicated for the management of diabetes in persons age 2 years and older. The Dexcom G6 System is intended to replace fingerstick blood glucose testing for diabetes treatment decisions. Interpretation of the Dexcom G6 System results should be based on the glucose trends and several sequential readings over time. The Dexcom G6 System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. The Dexcom G6 System is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. The Dexcom G6 System can be used alone or in conjunction with these digitally connected medical devices for the purpose of managing diabetes.
Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via	Same

	glucose oxidase chemical reaction	
Sample Type	Interstitial fluid	Same
Enzyme	Glucose Oxidase	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
General Device Characteristic Differences		
Sensor Calibration	Factory calibrated	Factory calibrated, optional manual calibration
Connected devices	Can be used in conjunction with digitally connected medical devices where the user manually controls actions for therapy decisions. Cannot be used with automated insulin delivery systems, including closed loop and insulin suspend systems.	Can be used in conjunction with digitally connected medical devices including automated insulin dosing systems.
Wireless Communication Protocol	Near Field Communication (NFC): (13.56 MHz RFID) Bluetooth Low Energy (BLE) 4.0	Bluetooth Core Specification v4.0
Anatomical Sensor Wear Locations	Back of the upper arm	Abdomen (age 2+ years) or upper buttocks (age 2-17 years)
Sensor Life	Up to 14 days (automatic sensor shut off)	Up to 10 days (automatic sensor shut off)
Situations where fingerstick is required to confirm sensor reading (adjunctive use)	• The user's symptoms do not match the glucose values displayed by the device.	• The user's symptoms do not match the glucose values displayed by the device.

	• The device does not show a glucose value. • During the first 12 hours of wear during which the check blood glucose icon is displayed.	• The device does not show a glucose value or trend arrow.
Storage Conditions (Sensor)	Temperature: 36°F – 82°F Humidity: 10-90%, noncondensing	Temperature: 36°F – 86°F Humidity: 10%-90% RH
Intended Use Population	Persons with diabetes mellitus age 4 and above	Persons with diabetes mellitus age 2 and above
Alerts and Alarms	Low Glucose alarm, High Glucose alarm, signal loss alarm, scan error, sensor error For Low and High Glucose alarms, a user - initiated action is required to see glucose values	Urgent low glucose (55 mg/dL), predictable low glucose, threshold low glucose, threshold high glucose, rising rate of glucose, falling rate of glucose, signal loss, sensor failure, transmitter failure.
Compatibility with Connected Devices	Compatible with digitally connected devices where the user manually controls actions for therapy decisions.	Compatible with digitally connected devices, including automated insulin dosing (AID) systems.
Primary Display Device	Reader	Hardware receiver or mobile app installed on compatible smart device
Trend Graph Glucose History	8 hours, 24-hour graph and other reports can be used to view logged data	1, 3, 6, 12, and 24 hours

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-“Medical Electrical Equipment -Part 1: General Requirements for Basic Safety and Essential Performance
- 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”

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

iCGM performance was evaluated in clinical studies described below in section C(3). Subjects wore two sensors concurrently, one on the back of each upper arm, to evaluate device precision.

In the Adult study (18 years and older), the mean paired absolute relative difference (between the 2 concurrently worn devices) was 8.1%; and the mean coefficient of variation (mean %CV) was 5.7%.

For pediatric age 4-5 years old, the mean paired absolute relative difference was 6.7%; and the mean %CV was 4.8%. For pediatric age 6-17 years, the mean paired absolute relative difference was 8.2%; and the mean %CV
was 5.8%.

Precision by subject age group:

Subject age group	Coefficient of Variation (%)	Paired Absolute Difference (mg/dL)	Paired Absolute Relative Difference (%)	Number of Subjects	Number of Paired Readings
Adults (18+)	5.7	12.4	8.1	146	26791
Pediatric 4-5 years	4.8	10.7	6.7	7	248
Pediatric 6-17 years	5.8	13.0	8.2	130	10623

2. Linearity:
The reportable range for the FreeStyle Libre 2 System is 40 to 400 mg/dL. Data supporting this claimed measurement range was generated in the clinical study described in Section C(3) below.

3. Analytical Specificity/Interference:
Certain endogenous and exogenous substances in the interstitial fluid may interfere with iCGM measurements. The types of potential interference and the extent of bias are dependent on the test principle of the sensor technology. For this device, ascorbic acid (vitamin C) has been shown to significantly interfere with system performance.

A clinical study was conducted to evaluate ascorbic acid interference for the FreeStyle Libre 2 System. This was a prospective, multi-center, single-arm study that enrolled 60 subjects at 4 sites. The study was designed to evaluate performance of the system in people with diabetes (age 18 and older) taking ascorbic acid. Each subject wore two sensors, one on the back of each upper arm, for a period of up to 10 days.

The interference effect of ascorbic acid on the Freestyle Libre 2 System was assessed by the difference (mg/dL) between CGM and comparator method (CM), in this case the Yellow Springs Instrument Life Sciences 2300 STAT Plus™ Glucose and Lactate Analyzer, readings at baseline and after each ascorbic acid doses. In this study, maximum bias was observed approximately 2 to 3 hours after each ascorbic acid dose.

The maximum average bias was +9.3 mg/dL after one1000 mg dose. The maximum average total biases were 18.4 mg/dL and 19.7 mg/dL (vs. baseline) after the second and third 1000 mg doses (given every 4 hours), respectively. Based on the clinical study to assess vitamin C interference and the bench studies, the expected positive bias from a single dose of 500 mg ascorbic acid (vitamin C) was estimated to be approximately 4.5 mg/dL.

The sponsor's bench dose response studies demonstrated that ascorbic acid interference is proportional to ascorbic acid concentration and is independent of the background glucose concentration. Therefore, there is significant risk that a positive bias of 10-20 mg/dL when true glucose values are low (e.g., 65-70) could lead users to miss clinically important low

glucose values. This bias is also in the context of an additional positive systemic bias in the Sensor in the low glucose range. In the absence of high dose vitamin C supplementation, information in the public domain suggests that the mean vitamin C intake (dietary intake and low dose supplement combined) of the intended use population is less than 500 mg per day. However, high dose vitamin C supplements (e.g., 1000 mg per dose) are common, and may be taken sporadically (e.g. at times of air travel or illness). In addition, some people take high dose supplements more than once per day. Finally, vitamin C levels not always clearly understood by lay users. For example, one gram may seem smaller than 500 mg to users who do not completely understand the metric system.

The Benefit/Risk Analysis completed at the time of the De Novo request for evaluation of automatic class III designation for the predicate device that resulted in the iCGM regulation states that "risks of this device include … Use of an iCGM as part of another digitally connected medical device system, such as an AID system, when the iCGM has inadequate analytical or clinical performance to support the intended use of the digitally connected device". The Special Controls proposed mitigating this risk by stating that "(4) The device must demonstrate clinically acceptable performance in the presence of clinically relevant levels of potential interfering substances that are reasonably present in the intended use population, including but not limited to endogenous substances and metabolites, foods, dietary supplements, and medications."

iCGM systems have multiple types of uses. They are generally used to generate glucose readings for the management of diabetes, to send alarms as a safety feature, and provide the convenience of digital connection to many devices. One of the proposed uses of the Freestyle Libre 2 System is to replace most blood glucose readings that users would need to make treatment decisions. We considered that some blood glucose meters have interference from vitamin C and other compounds, and labeling language has been frequently used to mitigate those risks. Labeling in the case of certain interferences for blood glucose meters is adequate mitigation because the user evaluates each reading prior to using it to make a treatment decision to determine whether it matches the way they feel and their current activities/actions. We determined that when the Freestyle Libre 2 system is for a use similar to a blood glucose meter, where users make decisions themselves for each reading, labeling is also adequate to mitigate the risks of this high bias due to vitamin C. For example, if a user sees sensor readings that look incorrect to them, they may realize that they took vitamin C, or take a blood glucose reading, and take safe action to adjust their response to the sensor readings.

The following statements have been placed in the device labeling to inform users of the risk of falsely high glucose results when taking vitamin C containing supplements:

- User Manual Warning: 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 healthcare professional to understand how long ascorbic acid is active in your body.
- Reader Screen Warning: Do not take high doses of vitamin C (more than 500 mg per day). This may falsely raise your Sensor readings. Supplements like Airborne or

Emergen-C have high doses of vitamin C. Read labeling for all supplements to determine vitamin C content.

However, when values from the Freestyle Libre 2 system are used automatically by an AID system to start or stop insulin or other medications, the user has less opportunity to recognize the interference prior to erroneous treatment. The risks introduced by this interference when used with an AID system are greater than for similar iCGM devices, yet the benefits are largely equal. Therefore, the benefits do not outweigh the risks for that use. Thus, the Freestyle Libre 2 system must not be used with AID systems.

4. Assay Reportable Range:
   The reportable range for the FreeStyle Libre 2 System is 40 to 400 mg/dL. Data supporting this claimed measurement range was generated in the clinical study described in Section C(3) below.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
   The FreeStyle Libre 2 sensor has a storage shelf-life of 9 months. Shelf-life was evaluated at 36° –82° Fahrenheit within the humidity range of 10% - 90%.

6. Detection Limit:
   If a glucose measurement is less than 40 mg/dL, the result will be displayed by the system as 'LO'. If the glucose measurement exceeds 400 mg/dL, the result will be displayed as 'HI'. Data supporting this claimed measurement range was generated in the clinical study described in Section C(3) below.

7. Assay Cut-Off:
   Not applicable.

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. Interstitial fluid is the only indicated matrix.

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):

Study Name	Patient Population	Study Objective
FreeStyle Libre Flash Glucose Monitoring System Accuracy Study (Study 1)	18 + years of age Type 1 or Type 2 Diabetes	Pivotal study to evaluate safety and effectiveness of the FreeStyle Libre Flash Glucose Monitoring System in comparison to laboratory glucose reference.
Effectiveness and Safety Study of the FreeStyle Libre Flash Glucose Monitoring System in Pediatric Populations (Study 2)	4 – 17 years of age Type 1 or Type 2 Diabetes	Pivotal study to evaluate safety and effectiveness of the FreeStyle Libre Flash Glucose Monitoring System in pediatric populations in comparison to laboratory glucose reference.

To demonstrate the accuracy performance of the FreeStyle Libre 2 Flash Glucose Monitoring System, two prospective clinical studies were conducted in the United States at five and four centers, respectively.

Study 1 enrolled 146 adult subjects with diabetes (91.1% with Type 1 diabetes and 8.9% with insulin-requiring Type 2 diabetes). Subjects wore 2 sensors for up to 14 days but accuracy analysis is based on the first applied sensor to each subject only. Subjects took part in up to three ten-hour clinical sessions that took place during four distinct periods: Days 1-3; Days 7-8; Days 9-12, and Days 13-14. During each clinic session, each subject's glucose was manipulated to observe data spanning the measuring range.

Study 2 enrolled 139 pediatric subjects with diabetes (98.6% with Type 1 diabetes and 1.4% with insulin-requiring Type 2 diabetes). Subjects wore 2 sensors for up to 14 days and accuracy analysis is based on the first applied sensor to each subject only. Subjects age six and older took part in one or two eight-hour clinical sessions. Self-monitoring blood glucose meter (SMBG) was used as the comparator method for subjects 4-5 years of age. Clinic sessions for each subject took place during four distinct periods: Days 1-2; Days 7-8; Days 9-12, and Days 13-. During each clinic session, glucose levels were manipulated in Subjects 11 years and older to observe data spanning the measuring range. Subjects 10 years and younger underwent observation only without glucose manipulation.

In both studies, accuracy of the FreeStyle Libre 2 Flash Glucose Monitoring System was evaluated by comparing iCGM glucose values to an FDA-cleared laboratory grade comparator method (YSI 2300) for subjects 6 years and older, and to SMBG in subjects 4-5 years old.

Glucose values were obtained from the system and from the comparator at the same or similar time. In both studies, absolute differences in mg/dL of values compared to the comparator method were calculated for all values below 70 mg/dL. For values of 70 mg/dL and above, percentage differences compared to the comparator method were calculated.

Data from the two clinical studies are presented in the tables below.

Percent and Point Accuracy by iCGM Glucose Range (Adults)

iCGM Glucose Range (mg/dL)	No. Pair	Percent within 15 mg/dL (95% LCL*)	Percent within 40 mg/dL (95% LCL)	Percent within 15% (95% LCL)	Percent within 40% (95% LCL)	Mean Bias, mg/dL (95% UCL*)
<70	3530	89.0 (86.7)	99.4 (99.1)			-2.9 (-1.9)
70-180	7785			75.9 (73.1)	99.6 (99.4)	-5.8 (-4.1)
>180	7420			91.5 (89.4)	100.0 (99.9)	-6.5 (-4.1)

*95% LCL is the lower bound of the 95% confidence limit and 95% UCL is the upper bound of the 95% confidence limit

Percent and Point Accuracy by iCGM Glucose Range (Pediatric*)

iCGM Glucose Range (mg/dL)	No. Pairs	Percent within 15 mg/dL (95% LCL)	Percent within 40 mg/dL (95% LCL)	Percent within 15% (95% LCL)	Percent within 40% (95% LCL)	Mean Bias, mg/dL (95% UCL)
<70	1002	82.7 (77.2)	98.6 (97.5)			-6.3 (-4.0)
70-180	2690			78.0 (74.8)	99.3 (98.9)	-3.8 (-1.7)
>180	2854			87.3 (84.4)	99.7 (99.5)	-1.4 (1.8)

*Includes children 6-17 years of age. No Comparator measurements were obtained for children 4-5 years of age.

Percent and Point Accuracy by Comparator Glucose Range (Adult)

CM Glucose Range (mg/dL)	No. Pair	Percent within 15 mg/dL (95% LCL)	Percent within 40 mg/dL (95% LCL)	Percent within 15% (95% LCL)	Percent within 40% (95% LCL)	Mean Bias, mg/dL (95% UCL)
<70	3468	95.3 (93.9)	100.0 (100.0)			1.5 (2.4)
70-180	7504			76.5 (73.8)	99.6 (99.4)	-4.8 (-3.5)
>180	7763			88.9 (86.3)	99.9 (99.8)	-8.7 (-6.3)

Percent and Point Accuracy by Comparator Glucose Range (Pediatric*)

CM Glucose Range (mg/dL)	No. Pairs	Percent within 15 mg/dL (95% LCL)	Percent within 40 mg/dL (95% LCL)	Percent within 15% (95% LCL)	Percent within 40% (95% LCL)	Mean Bias, mg/dL (95% UCL)
<70	882	94.9 (92.1)	100.0 (100.0)			2.1 (3.3)
70-180	2743			75.6 (72.2)	99.0 (98.5)	-2.2 (-0.5)
>180	2921			87.7 (84.9)	99.1 (97.9)	-4.3 (-0.8)

*Includes children 6-17 years of age. No comparator measurements were obtained for children 4-5 years of age

Percent of iCGM values within 20% of Comparator Glucose Values

iCGM Glucose Range (mg/dL)	No. Pairs	No. Subject	Percent within 20% (95% LCL)
Adult (18 years and up)	18735	144	90.2 (88.7)
Pediatric (6-17 years)	6546	129	90.3 (88.1)
Pediatric (4-5 years old)*	341	8	85.4 (80.3)

* Subjects 4-5 years old were compared to an SMBG meter

Percent values within 15%/15 mg/dL, 20%/20 mg/dL and 40%/40 mg/dL stratified by glucose ranges of <54, 54-69, 70-180. 181-250 and >250 mg/dL for iCGM and laboratory comparator were also provided. For pediatric subjects ages 4-5, values were compared to SMBG.

Accuracy to Comparator within iCGM Glucose Ranges (Adult)

CGM Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mg/dL)	(MARD*) (%)
<54	518	85.9	93.8	99.4				-6.4	13.8
54-69	3012	89.5	94.2	99.1				-3.3	10.8
70-180	7785				76.5	86.6	99.2	-4.8	10.6
181-250	3037				89.1	95.0	99.9	-10.1	7.8
>250	4383				94.0	97.9	100.0	-6.3	6.1

*Mean Absolute Relative Difference

Accuracy to Comparator within iCGM Glucose Ranges (Pediatric)

CGM Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mg/dL)	MARD (%)
<54	139	71.9	79.1	97.1				-9.9	17.1
54-69	863	86.4	90.5	97.1				-4.9	12.0
70-180	2690				77.4	87.6	98.7	-3.4	10.6
181-250	1236				86.0	94.7	99.7	-8.9	8.3
>250	1618				92.2	97.7	99.8	-2.2	7.2

Accuracy to Comparator within Comparator Glucose Ranges (Adult)

CM Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mg/dL)	MARD (%)
<54	440	91.1	97.5	100.0				7.4	15.5
54-69	3028	94.7	98.6	100.0				1.5	10.2
70-180	7504				77.5	86.9	99.4	-4.8	10.4
181-250	2937				87.9	93.7	99.7	-8.0	8.0
>250	4826				90.9	95.9	99.7	-11.8	6.9

Accuracy to Comparator within Comparator Glucose Ranges (Pediatric)

CM Glucose Level (mg/dL)	Number of CGM-Reference Pairs	Percent Within ±15 mg/dL	Percent Within ±20 mg/dL	Percent Within ±40 mg/dL	Percent Within ±15%	Percent Within ±20%	Percent Within ±40%	Mean bias (mg/dL)	MARD (%)
<54	131	93.9	98.5	100.0				6.6	14.2
54-69	751	96.5	98.8	100.0				1.0	9.3
70-180	2743				74.3	84.8	98.0	-3.0	11.4
181-250	1104				86.6	92.9	99.0	-3.9	8.4
>250	1817				90.2	97.5	99.9	-10.2	7.6

Concurrence of iCGM values compared to the comparator method across the entire measuring range was also evaluated. iCGM glucose ranges of <40, 40-60, 61-80, 81-120, 121-160, 161-200, 201-250, 251-300, 351-400 and >400 mg/dL were evaluated against the comparator glucose ranges and percent of iCGM values within those ranges were reported.

Concurrence Analysis by iCGM Glucose Level (Adult)

CGM (mg/dL)	CM(mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400	
<40	20.0	20.0	40.0	20.0	.	.	.	.	.	.	.	5
40-60	0.4	52.9	43.3	3.3	.	0.1	.	.	.	.	.	1889
61-80	.	18.9	62.7	18.1	0.4	0.0	.	.	.	.	.	3090
81-120	.	0.2	11.0	70.1	17.8	0.8	0.1	.	.	.	.	3040
121-160	.	.	0.1	9.1	69.9	18.9	1.6	0.3	0.2	.	.	2407
161-200	.	.	.	.	10.6	60.6	26.9	1.6	0.3	.	.	1745
201-250	.	.	.	.	.	7.0	65.5	25.6	1.9	0.1	.	2181
251-300	.	.	.	.	.	0.1	8.4	66.9	22.7	1.8	0.1	2327
301-350	.	.	.	.	.	.	0.4	13.6	68.8	16.0	1.2	1522
351-400	.	.	.	.	.	.	.	0.6	27.5	63.3	8.6	534
>400	.	.	.	.	.	.	.	.	2.5	62.8	34.7	121

Concurrence Analysis by iCGM Glucose Level (Pediatric)

CGM (mg/dL)	CM(mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400	
<40	.	50.0	50.0	.	.	.	.	.	.	.	.	2
40-60	0.6	48.6	42.5	7.8	0.6	.	.	.	.	.	.	527
61-80	.	12.1	61.9	24.3	1.7	.	.	.	.	.	.	915
81-120	.	0.2	11.2	69.0	18.2	1.3	0.1	.	.	.	.	1006
121-160	.	.	.	11.4	71.0	15.8	1.8	.	.	.	.	868
161-200	.	.	.	0.1	18.2	61.3	20.1	0.3	.	.	.	703
201-250	.	.	.	.	0.2	9.6	55.3	33.6	1.2	0.1	.	909
251-300	.	.	.	.	.	0.1	14.1	60.8	23.7	1.3	.	818
301-350	.	.	.	.	.	.	0.3	24.8	58.2	16.5	0.2	593
351-400	.	.	.	.	.	1.0	.	0.5	33.8	59.4	5.3	207
>400	.	.	.	.	.	.	.	4.4	6.7	33.3	55.6	45

Concurrence Analysis by Comparator Glucose Level (Adult)

CM (mg/dL)	CGM (mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400	
<40	12.5	87.5	.	.	.	.	.	.	.	.	.	8
40-60	0.1	62.9	36.6	0.4	.	.	.	.	.	.	.	1591
61-80	0.1	26.4	62.6	10.8	0.1	.	.	.	.	.	.	3093
81-120	0.0	2.1	18.8	71.7	7.3	.	.	.	.	.	.	2971
121-160	.	.	0.5	22.3	69.6	7.7	.	.	.	.	.	2418
161-200	.	0.1	0.1	1.5	26.9	62.5	9.0	0.1	.	.	.	1694
201-250	.	.	.	0.1	1.8	21.9	66.8	9.1	0.3	.	.	2139
251-300	.	.	.	.	0.3	1.2	23.7	66.0	8.8	0.1	.	2359
301-350	.	.	.	.	0.3	0.3	2.3	29.8	58.9	8.3	0.2	1777
351-400	.	.	.	.	.	.	0.3	6.1	34.7	48.1	10.8	703
>400	.	.	.	.	.	.	.	1.9	16.7	42.6	38.9	108

Concurrence Analysis by Comparator Glucose Level (Pediatric)

CM (mg/dL)	CGM (mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400	
<40	.	100.0	.	.	.	.	.	.	.	.	.	3
40-60	0.3	69.2	30.0	0.5	.	.	.	.	.	.	.	370
61-80	0.1	24.8	62.6	12.5	.	.	.	.	.	.	.	904
81-120	.	3.9	21.0	65.7	9.4	0.1	.	.	.	.	.	1057
121-160	.	0.3	1.7	19.3	65.0	13.5	0.2	.	.	.	.	948
161-200	.	.	.	1.9	20.4	64.2	13.0	0.1	.	0.3	.	671
201-250	.	.	.	0.1	2.1	18.1	64.7	14.8	0.3	.	.	778
251-300	.	.	.	.	.	0.2	32.0	52.1	15.4	0.1	0.2	954
301-350	.	.	.	.	.	.	1.8	31.1	55.4	11.2	0.5	623
351-400	.	.	.	.	.	.	0.4	4.4	39.5	49.6	6.0	248
>400	.	.	.	.	.	.	.	.	2.7	29.7	67.6	37

Trend Accuracy

Trend accuracy describes the accuracy of the sensor during times of rapidly changing glucose and is characterized by slopes, such as from > 2mg/dL/min to <-2 mg/dL/min. Trend accuracy was assessed by the concurrence rate of the glucose rate of change from the iCGM and the corresponding comparator values for each iCGM-comparator measurement pair.

Concurrence Analysis by Glucose Rate of Change (Adult)

CGM Rate Range (mg/dL/min)	CM Rate Range (mg/dL/min)						N
	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2	
<-2	34.4	44.9	18.3	2.2	0.3	.	323
[-2, -1)	6.8	46.6	41.2	4.0	0.9	0.5	1090
[-1, 0)	1.2	8.3	67.1	19.7	2.6	1.2	9389
[0, 1]	0.9	3.4	26.0	46.9	15.5	7.3	5420
(1, 2]	0.1	1.7	7.7	31.6	38.4	20.5	1151
>2	0.2	0.2	3.1	14.6	32.9	49.0	881

Concurrence Analysis by Glucose Rate of Change (Pediatric*)

CGM Rate Range (mg/dL/min)	CM Rate Range (mg/dL/min)						N
	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2	
<-2	44.1	44.7	8.8	2.4	.	.	170
[-2, -1)	11.4	49.5	32.8	5.2	0.4	0.6	463
[-1, 0)	2.1	11.2	60.0	20.8	3.9	1.9	2587
[0, 1]	1.4	5.6	25.2	43.2	14.8	9.7	2095
(1, 2]	0.2	2.6	10.4	29.7	35.5	21.5	498
>2	.	0.9	4.2	15.0	29.7	50.2	448

*includes children 6-17 years of age. No CM measurements were obtained for children 4-5 years of age

Agreement When iCGM Reads 'LO' or 'HI'

The FreeStyle Libre 2 Glucose Monitoring System reports glucose readings between 40 and 400 mg/dL. When the system determines that the glucose reading is below 40 mg/dL, it will display 'LO' whenever the sensor is scanned. When the system determines that the glucose reading is above 400 mg/dL, it will display 'HI' whenever the sensor is scanned. Because the system does not display glucose values below 40 mg/dL or above 400 mg/dL, the comparisons to the actual blood glucose levels (as determined by the comparator) when the iCGM value is classified as 'LO' or 'HI' are evaluated separately. The cumulative percentages of when the comparator values were less than certain glucose values (for 'LO') and when comparator values were more that certain glucose values (for 'HI') are presented in the tables below.

Concurrence Analysis with 'LO' CGM Reading (Adult)

CGM-Reference Pairs	Comparator (mg/dL)					N
	<50	<60	<70	<80	≥ 80	
n	1	2	2	4	1	5
Cumulative %	20.0	40.0	40.0	80.0	20.0	

Concurrence Analysis with 'LO' CGM Reading (Pediatric*)

CGM-Reference Pairs	Comparator (mg/dL)					N
	<50	<60	<70	<80	≥ 80	
n	0	1	2	2	0	2
Cumulative %	0.0	50.0	100.0	100.0	0.0	

*includes children 6-17 years of age. No CM measurements were obtained for children 4-5 years of age

Concurrence Analysis with 'HI' CGM Reading (Adult)

CGM-Reference Pairs	Comparator (mg/dL)				N
	>350	>300	>250	>250	
n	118	121	121	0	121
Cumulative %	97.5	100.0	100.0	0.0	

Concurrence Analysis with 'HI' CGM Reading (Pediatric*)

CGM-Reference Pairs	Comparator (mg/dL)				N
	>350	>300	>250	>250	
n	40	43	45	0	45
Cumulative %	88.9	95.6	100.0	0.0	

*includes children 6-17 years of age. No CM measurements were obtained for children 4-5 years of age

Alarm Performance

The tables in this section show the accuracy of the System's Low and High Glucose Alarms. The Alarm Rate tells the user how often the alarm is right or wrong. The Detection Rate tells the user how often the System is able to recognize and notify the user about a low or high glucose event (within 15 minutes before or after the event).

Low Glucose Alarm Performance

True Alarm Rate: Percentage of time the alarm issued, and blood glucose was below the alarm level within 15 minutes before or after the alarm.

False Alarm Rate: Percentage of time the alarm issued, and blood glucose was not below the alarm level within 15 minutes before or after the alarm.

Detection Rate: Percentage of time blood glucose was below the alarm level and the alarm issued within 15 minutes before or after the glucose event.

Missed Detection Rate: Percentage of time blood glucose was below the alarm level and the alarm didn't issue within 15 minutes before or after the glucose event.

Low Glucose Alarm Performance (Adult)

Low Glucose Alarm level (mg/dL)	Alarm Rate			Detection Rate		
	Hypo Alerts (n)	True Alarm Rate (%)	False Alarm Rate (%)	Hypo Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
60	9861	72.6	27.4	1527	75.7	24.3
70	21504	86.0	14.0	3652	89.3	10.7
80	32784	91.3	8.7	4753	97.3	2.7
90	41299	93.6	6.4	5591	98.5	1.5

Low Glucose Alarm Performance (Pediatric*)

Low Glucose Alarm level (mg/dL)	Alarm Rate				Detection Rate	
	Hypo Alerts (n)	True Alarm Rate (%)	False Alarm Rate (%)	Hypo Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
60	2780	62.9	37.1	373	87.4	12.6
70	6363	80.3	19.7	963	93.5	6.5
80	9747	85.6	14.4	1318	96.4	3.6
90	12550	92.2	7.8	1656	97.3	2.7

* Includes children 6-17 years of age. No Comparator measurements were obtained for children 4-5 years of age.

High Glucose Alarm Performance

True Alarm Rate: Percentage of time the alarm issued, and blood glucose was above the alarm level within 15 minutes before or after the alarm.

False Alarm Rate: Percentage of time the alarm issued, and blood glucose was not above the alarm level within 15 minutes before or after the alarm.

Detection Rate: Percentage of time blood glucose was above the alarm level and the alarm issued within 15 minutes before or after the glucose event.

Missed Detection Rate: Amount of time blood glucose was above the alarm level and the alarm didn't issue within 15 minutes before or after the glucose event.

High Glucose Alarm Performance (Adult)

High Glucose Alarm level (mg/dL)	Alarm Rate			Detection Rate		
	Hyper Alerts (n)	True Alarm Rate (%)	False Alarm Rate (%)	Hyper Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
120	105544	99.1	0.9	11417	98.2	1.8
140	93574	99.1	0.9	10152	98.1	1.9
180	74290	99.2	0.8	8080	97.8	2.2
200	66039	99.2	0.8	7269	97.1	2.9
220	57549	99.0	1.0	6390	96.9	3.1
240	48733	98.4	1.6	5550	95.6	4.4
300	21512	96.3	3.7	2672	90.0	10.0

High Glucose Alarm Performance (Pediatric*)

High Glucose Alarm level (mg/dL)	Alarm Rate			Detection Rate		
	Hyper Alerts (n)	True Alarm Rate (%)	False Alarm Rate (%)	Hyper Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)
120	34176	98.8	1.2	4441	98.2	1.8
140	30107	98.0	2.0	3945	98.4	1.6
180	22430	98.4	1.6	3125	98.0	2.0
200	19425	98.0	2.0	2791	98.0	2.0
220	16371	98.2	1.8	2492	96.9	3.1
240	13359	98.0	2.0	2172	95.7	4.3
300	6064	90.8	9.2	962	91.0	9.0

* Includes children 6-17 years of age. No Comparator measurements were obtained for children 4-5 years of age.

Sensor Stability

Sensor stability describes the performance of the sensor over the sensor lifetime. Sensors can be worn for up to 14 days. Performance was estimated by calculating the mean of the absolute relative differences between iCGM and comparator measurement and percentage of device readings within 15 mg/dL or 15% (15/15%), 20 mg/dL or 20% (20/20%) and 40 mg/dL or 405 (40/40%) of the comparator values during the beginning, early middle, late middle, and end of the wear period. These times were defined as follows:

- Beginning (Adult Days 1-3, Pediatric: Days 1-2)
- Early Middle (Adult: Days 7-8, Pediatric: Days 7-8),
- Late Middle (Adult: Days 9-12, Pediatric: Days 9-12), and
- End (Adult: Days 13-14, Pediatric: Days 13-14).

The mean absolute relative difference (MARD) and agreement rates with the comparator method were evaluated over 14 day life of the sensor.

Sensor Accuracy Relative to Comparator Over the Wear Duration (Adult)

Wear Period	Number of CGM-reference pairs	MARD (%)	Within ±15%/ ±15mg/dL	Within ±20%/ ±20mg/dL	Within ±40%/ ±40mg/dL
Beginning	6955	9.9	83.4	90.4	99.3
Early Middle	4522	8.5	87.7	94.5	99.8
Late Middle	3503	8.8	86.8	93.4	99.7
End	3755	9.1	86.4	92.9	100.0

Sensor Accuracy Relative to Comparator Over the Wear Duration (Pediatric*)

Wear Period	Number of CGM-reference pairs	MARD (%)	Within ±15% / ±15mg/dL	Within ±20% / ±20mg/dL	Within ±40% / ±40mg/dL
Beginning	1828	10.7	79.6	88.5	98.6
Early Middle	1642	8.0	89.5	94.2	98.5
Late Middle	1534	9.7	83.6	92.9	99.5
End	1542	10.2	82.6	91.1	99.3

* Includes children 6-17 years of age. No Comparator measurements were obtained for children 4-5 years of age.

Sensor Life

The Sensor can be worn for up to 14 days. 146 Sensors were evaluated in the Adult Study and 139 Sensors were evaluated in the Pediatric Study to determine how many days of readings each Sensor provided. Of the 146 Sensors in the Adult study, 71.1% lasted until the final day of use. Six (6) Sensors (4.1%) had “early sensor shut-off” where the Sensor algorithm detected that the Sensors did not function as intended and presented the user with a “Replace Sensor” message. In the Pediatric study, 78.1% of the Sensors lasted until the final day of use. Three (3) Sensors (2.2%) had “early sensor shut-off” and presented the user with a “Replace Sensor” message.

Sensor Survival Rate Over Wear Duration (Adult)

Day of Wear	Number of Sensors	Survival Rate (%)
1	145	99.3
2	142	97.3
3	140	95.9
4	137	93.8
5	134	93.8
6	133	91.1
7	132	90.4
8	127	87.0
9	123	84.9
10	119	82.2
11	112	77.3
12	111	76.6
13	104	71.8
14	100	71.1

Sensor Survival Rate Over Wear Duration (Pediatric)

Day of Wear	Number of Sensors	Survival Rate (%)
1	137	98.6
2	136	97.8
3	134	97.1
4	133	96.4
5	133	96.4
6	133	96.4
7	133	96.4
8	131	94.9
9	126	91.3

Day of Wear	Number of Sensors	Survival Rate (%)
10	124	89.9
11	122	88.4
12	120	87.0
13	114	83.4
14	104	78.1

A separate analysis was done regarding early sensor terminations due to sensor knock-offs (when a sensor falls off due to being forcibly pushed off). All adult and pediatric subjects wore two sensors (one on each arm) and all sensors worn within the study were included in the sensor survival rate analysis. It was observed that sensors worn on the patient's dominant arm were more likely to be knocked off than those worn on the non-dominant arm.

In a previously conducted adult sensor wear study, participants cleaned the sensor application site with soap and water prior to sensor application. It was observed that those subjects who cleaned the application site appropriately were able to achieve the full 14-day sensor wear time. To mitigate the risk of early sensor termination due to sensor knock off and failure to clean insertion site, the following information was provided in the User Guide:

Wash application site 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. Note: The area MUST be clean and dry following these instructions, or the Sensor may not stay on for the full 14-day wear period.

A third clinical study was also conducted to further evaluate wear duration in subjects who first washed the insertion site with a plain soap and water, according to the full instructions in the labeling and wore only a single Sensor. Of the 39 Sensors evaluated in this study, 38 sensors (97%) lasted until the final day of use (14 days).

Glucose Reading Availability

The System is designed to show a Sensor glucose reading after each scan that is performed throughout the wear period after the start-up time. As such, the capture rate characterizes the reliability of the communication between components of the system.

Glucose Reading Capture Rate Over Wear Duration (Adult)

Day of Wear	Number of Sensors	Capture Rate (%)
1	146	98.3
2	145	98.1
3	143	98.3
4	140	98.3
5	138	98.4
6	135	98.3
7	134	98.4
8	131	98.4
9	128	98.4
10	123	98.4
11	120	98.4
12	113	98.5
13	112	98.5
14	104	98.6

Glucose Reading Capture Rate Over Wear Duration (Pediatric)

Day of Wear	Number of Sensors	Survival Rate (%)
1	139	94.6
2	137	94.9
3	136	95.2
4	133	95.3
5	134	95.5
6	133	95.6
7	133	96.0
8	133	95.9
9	130	95.7

Day of Wear	Number of Sensors	Survival Rate (%)
10	125	95.6
11	125	95.6
12	122	95.8
13	119	95.9
14	116	95.8

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

F Other Supportive Instrument Performance Characteristics Data:

Human Factors
Human factors and usability testing of the FreeStyle Libre 2 System 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.

Software Verification and Validation
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 embedded software is acceptable for its intended use.

Biocompatibility
Biocompatibility testing in accordance with ISO10993-1 and FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process," June 16, 2016 was performed on Sensor materials including the outer Sensor, casing, adhesive pad, and sensor tail. Biological evaluation included cytotoxicity, genotoxicity, irritation, sensitization, and system toxicity testing. All biocompatibility testing met the acceptance criteria.

Biocompatibility testing on the user-contacting materials on the Reader and Sensor sub-components (Patch mount, adhesive pad, plug components, introducer sharp and sensor component) was leveraged from previous FreeStyle Libre Flash CGM systems as these components remained unchanged.

Sterilization
Electron beam sterilization validation was performed per ISO11137-1 and ISO 11137-2. Sterilization validation confirmed that the Sterility Assurance Level (SAL) of 10^{-6} is achieved with the selected target dose of 25kGy. The sterilization dose was established by the VDmax25 method described in ISO 11137-2. All sterilization testing conducted met the acceptance criteria, and supports sterility of the patient contact components of the device.

Shelf Life and Stability
The Sensor Kit shelf life stability testing supports a shelf life of 9 months. Additional testing was conducted to support sensor kit storage temperature range of 36°F and 82°F. Results demonstrated no impact to sensor stability when stored at these storage temperatures.

Packaging Integrity/Shipping Integrity
. Packaging and shipping integrity testing evaluated the Sensor Kits and Reader Kits in accordance with EN ISO 11607-1, EN ISO 11607-2, ASTM D4169-14, and ASTM D4332-13 guidelines. All tested units passed the testing requirements of all distribution tests.

Electromagnetic Compatibility
Electromagnetic compatibility (EMC) testing was performed for the FreeStyle Libre 2 System to verify that the system is able to withstand the electromagnetic interference in compliance with IEC 60601-1-2, IEC CISPR 11 and Federal Communication Commission Regulations Part 15.209 and 15.225. EMC coexistence testing was also performed to confirm that the Reader and Patch remain 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. Testing was also performed to demonstrate compliance of the FreeStyle Libre 2 System with Category M of RTCA DO-160:

- The FreeStyle Libre 2 Reader and Patch underwent electromagnetic compatibility (EMC) and electromagnetic immunity (EMI) testing and both demonstrated compliance with IEC 60601-1-2:2014.
- The FreeStyle Libre 2 Reader and Patch were exposed to electrostatic events (i.e., static electricity discharges from operators directly and from personnel to adjacent objects) in

accordance with IEC 61000-4-2 Edition. Electrostatic discharge testing was performed at ± 8 kV for contact discharge and at ± 15 kV for air discharge. The FreeStyle Libre 2 System met the performance requirements for the ESD Immunity Test.

- Testing was performed to determine compliance with Federal Communications Commission (FCC) standards. The FreeStyle Libre 2 System successfully demonstrated compliance with FCC Part 15 Subpart C §15.247 (2016) and FCC Part 15 Subpart B (2016).
- The FreeStyle Libre 2 System demonstrated compliance with airworthiness requirements per the Federal Aviation Administration (FAA) Advisory Circular RTCA/DO-160 Edition G section 21, Category M (RF Emission specification).
- The FreeStyle Libre 2 System 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.
- Conducted emissions and radiated emissions testing for the FreeStyle Libre 2 System was performed in accordance with IEC/EN 60601-1-2:2014 and CISPR 11. The FreeStyle Libre 2 System demonstrated that maximum emissions did not exceed the limits established for residential or home use (Class B).

Electrical Safety
The basic safety and essential performance of the FreeStyle Libre 2 System was evaluated to IEC 60601-1:2006/A1:2013. Tested units included the FreeStyle Libre 2 Reader and Patch and both demonstrated compliance to the requirements of IEC 60601-1:2006/A1:2013.

Environmental Testing
Environmental testing on the FreeStyle Libre 2 System was performed in accordance with IEC 60601-1 to ensure the device specifications for operating temperature, operating humidity, operating pressure, impact resistance, vibration resistance, shock resistance, drop resistance, and storage conditions were met.

Blood Glucose Meter Functionality
The FreeStyle Precision Neo Blood Glucose Test Strips cleared under K171941 are compatible for use with the FreeStyle Libre 2 Reader's built-in blood glucose meter for quantitative measurement of glucose from fresh capillary whole blood drawn from fingertips. Studies have been conducted to support the use of the FreeStyle Libre 2 Reader's built-in meter with the FreeStyle Precision Neo Blood Glucose Test Strips.

Interoperability
The FreeStyle Libre 2 System incorporates an approach for interoperability developed in alignment with FDA guidance, "Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices," September 6, 2017, which includes expectations, requirements, and interface specifications to potential interoperable devices. In addition, the ADC approach to interoperability includes working with connected device companies regarding contractual approaches, interfaces for data communication and exchange, and post-market reporting procedures and responsibilities with respect to managing complaints

(e.g., who is responsible for investigating and reporting complaints, malfunctions, and adverse events).

Cybersecurity
ADC has provided cybersecurity risk management documentation for the FreeStyle Libre 2 System 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.

Proposed Labeling
The FreeStyle Libre 2 Flash Glucose Monitoring System labeling is sufficient and satisfies the requirements of 21 CFR Parts 801 and 809, and the special controls for this type of device.

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.