June 12, 2020

Abbott Diabetes Care Inc.
Naveen Thuramalla
DVP, Quality Assurance and Regulatory Affairs
1360 South Loop Road
Alameda, CA 94502

Re: K193371
Trade/Device Name: FreeStyle Libre 2 Flash Glucose Monitoring System
Regulation Number: 21 CFR 862.1355
Regulation Name: Integrated Continuous Glucose Monitoring System
Regulatory Class: Class II
Product Code: QLG, NBW
Dated: May 8, 2020
Received: May 11, 2020

Dear Naveen Thuramalla:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm, Ph.D.
Acting Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193371

Device Name
FreeStyle Libre 2 Flash Glucose Monitoring System

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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1. 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: **K193371**

1.1 Submitter:

Abbott Diabetes Care, Inc.
1360 South Loop Road
Alameda, CA 94502

Contact: Naveen Thuramalla
Title: DVP Quality Assurance and Regulatory Affairs
Phone: 510-239-2618
Fax: (510) 864-4791
Email: naveen.thuramalla@abbott.com

1.2 Device Names and Classification:

Name of Device:	FreeStyle Libre 2 Flash Glucose Monitoring System
Common Name:	Integrated Continuous Glucose Monitoring System, Factory Calibrated, Not for use with automated insulin delivery systems
Regulatory Section:	21 CFR 862.1355, 21 CFR 862.1345
Classification:	Class II
Product Code(s):	QLG, NBW
Review Panel:	Clinical Chemistry

1.3 Predicate Device

Predicate Device:	Dexcom G6 Continuous Glucose Monitoring System, DEN170088

1.4 Indications for 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 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.

Contraindications

- Automated Insulin Delivery: 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.

1.5 Device Description

The FreeStyle Libre 2 Flash Glucose Monitoring System (herein 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 consists of two primary components: a sensor that transmits via Bluetooth Low Energy (BLE), and a BLE enabled display device (Reader). User-initiated RFID scanning provides the user with real-time glucose measurements (glucose values) accompanied by trend information (glucose arrows) and historical glucose information (glucose graph). The user may use the sensor glucose results and information provided by the System in making treatment decisions. The System also provides configurable alerts and alarms designed to warn the user of Low Glucose, High Glucose or Signal Loss.

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. During Sensor application, the sensor tail is inserted about 5.5 millimeters below the surface of the skin through the guidance of a needle. The needle is retracted back into the applicator after insertion. The Sensor continuously measures glucose concentration in interstitial fluid every minute 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 that uses RFID communication to start new sensors, to scan sensors to display and record data and uses BLE communication to issue alarms that notify the user when glucose values pass high or low thresholds, when enabled. The Reader also includes a built-in strip port with blood glucose functionality as a convenience for users (which is intended to work with the FreeStyle Precision Neo Blood Glucose test strips, cleared under K171941), and a user interface that includes event logging features.

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. This system is not compatible with AID systems, including insulin suspend systems.

1.5.1 Test Principle

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

1.6 Substantial Equivalence

A. Predicate Device Name:

Dexcom G6 Continuous Glucose Monitoring System

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

DEN170088

C. Comparison with Predicate:

The similarities and differences between the FreeStyle Libre 2 Flash Glucose Monitoring System and the predicate device, Dexcom G6 (DEN170088) are highlighted in the tables below:

Similarities		
Item	**FreeStyle Libre 2 Flash Glucose Monitoring System**	**Dexcom G6 Continuous Glucose Monitoring System (DEN170088)**
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 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 Dexcom G6 Continuous Glucose Monitoring System (Dexcom G6 System) is 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.
Device Type	Integrated CGM	Same
Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction	Same
Sample Type	Interstitial fluid	Same

Similarities		
Item	**FreeStyle Libre 2 Flash Glucose Monitoring System**	**Dexcom G6 Continuous Glucose Monitoring System (DEN170088)**
Enzyme	Glucose oxidase	Same
Clinical Application	Management of diabetes mellitus	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

Differences		
Item	**FreeStyle Libre 2 Flash Glucose Monitoring System**	**Dexcom G6 Continuous Glucose Monitoring System (DEN170088)**
Situations where fingerstick test is required to confirm sensor reading (adjunctive use)	• 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 user's symptoms do not match the glucose values displayed by the device. • The device does not show a glucose value or a trend arrow.
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
Sensor Calibration	Factory calibrated	Factory calibrated, with optional user calibration
Glucose reading update interval	Every 1 minute	Every 5 minutes
Wireless communications protocol	Near Field Communication (NFC): (13.56 MHz RFID) Bluetooth Low Energy (BLE) 4.0	Bluetooth Core Specification v4.0
Communications range	20 feet unobstructed	20 feet unobstructed
Glucose Trend Arrow	↑, > +2 mg/dL/min ↗, +1 and +2 mg/dL/min →, -1 to +1 mg/dL/min ↘, -2 to -1 mg/dL/min ↓, < -2 mg/dL/min	↑↑, > +3mg/dL/min ↑, +2 to +3 mg/dL/min ↗, +1 to +2mg/dL/min →, -1 to +1 mg/dL/min ↘, -2 to -1 mg/dL/min ↓, -3 to -2 mg/dL/min ↓↓, < -3mg/dL/min
Anatomical sensor wear locations	Back of the upper arm	Abdomen (age 2+ years) or upper buttocks (age 2-17 years)
Sensor warm up time	1 hour	2 hours
Sensor life	Up to 14 days (automatic sensor shut off)	Up to 10 days (automatic sensor shut off)
Storage Conditions (Sensor)	Temperature: 36°F – 82°F Humidity: 10-90% RH	Temperature: 36°F – 86°F Humidity: 10%-90% RH
Intended Use Population	Persons with diabetes age 4 and above	Persons with diabetes age 2+ years
Alerts and Alarms	Low Glucose Alarm, High Glucose Alarm, Signal Loss Alarm, Scan Error, Sensor Error	Urgent low glucose (55 mg/dL), predictable low glucose, threshold low glucose, threshold high

Differences		
Item	**FreeStyle Libre 2 Flash Glucose Monitoring System**	**Dexcom G6 Continuous Glucose Monitoring System (DEN170088)**
	For Low and High Glucose alarms, a user-initiated action is required to see glucose reading.	glucose, rising rate of glucose, falling rate of glucose, signal loss, sensor failure, transmitter failure.
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

1.7 Summary of Performance Testing

1.7.1 Analytical Performance

a. Reproducibility/Precision

iCGM performance was evaluated in clinical studies described below in **Section 1.7.3**. In Study 1, all subjects wore two sensors concurrently, one on the back of each upper arm, to evaluate device precision. A total of 26,791 paired readings from 146 subjects were evaluated. Mean coefficient of variation (Mean %CV) was 5.7%.

In Study 2, all subjects wore two sensors concurrently, one on the back of each upper arm, to evaluate device precision. For pediatric age 4-5, a total of 248 paired readings from 7 subjects were evaluated; mean coefficient of variation (Mean %CV) was 4.8%. For pediatric age 6-17, a total of 10,623 paired readings from 130 subjects were evaluated; 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

b. Linearity/Assay Reportable Range

The reportable range for the FreeStyle Libre 2 System is 40 to 400 mg/dL.

c. Traceability, Stability, Expected Values (Control, Calibrators, or Methods)

The FreeStyle Libre 2 sensor has a storage life of 9 months. Shelf-life was evaluated at 36° – 82° Fahrenheit within the humidity range of 10% - 90%.

d. 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 1.7.3** below.

e. Analytical Specificity:

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 technology, ascorbic acid (vitamin C) has been shown to interfere with the system performance when present in the body at concentrations higher than the recommended daily allowance. During the pivotal clinical studies, all medications and vitamins for which the subject was using or had used over the course of the study along with frequency of use were recorded. Both studies did not include exclusion criteria based on medications or vitamin use.

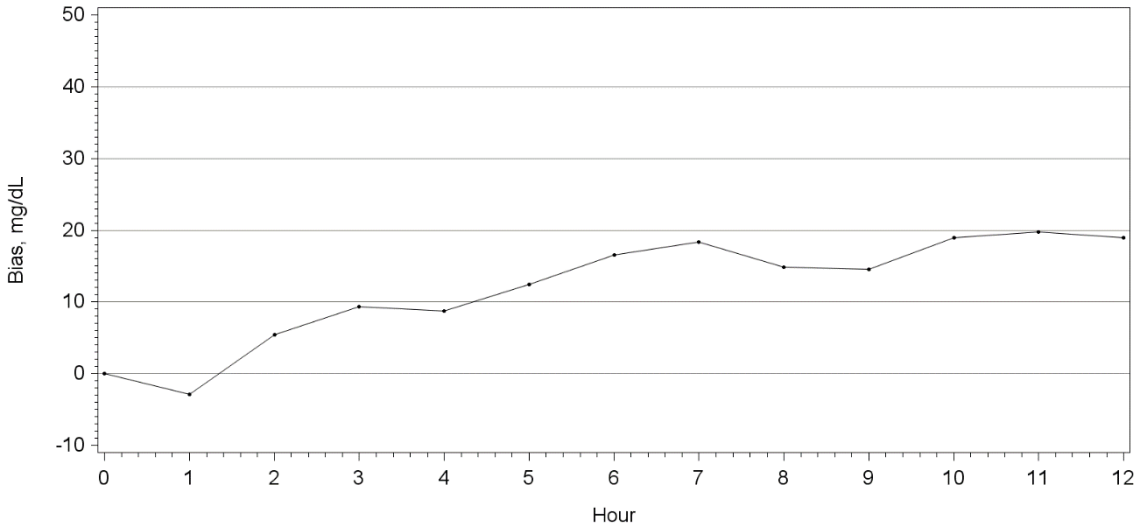
A clinical study was conducted to evaluate ascorbic acid interference for the FreeStyle Libre 2 System. It is a prospective, multi-center, single-arm study that enrolled 60 subjects at 4 sites. The study was designed to evaluate performance of the System in people with diabetes (age 18 and older) taking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

Subjects participated in one clinic session between sensor wear days 4 and 10. During the in-clinic visit, data was collected over a 13-hour period. Each subject had a one-hour baseline phase where venous blood was collected every 10 minutes. After this first hour, a dose of 1000 mg ascorbic acid was given with a meal and venous samples were collected every 20 minutes for the next four hours. Subjects then received a second dose of 1000 mg ascorbic acid with a meal and measurements were taken every 20 minutes for another 4 hours. Subsequently, a third dose of 1000 mg ascorbic acid was given with a meal and measurements were taken every 20 minutes for 4 more hours.

Accuracy performance of the System was assessed by the mean difference (mg/dL) between GM and YSI readings pre and post- ascorbic acid doses. For each matched pair of CGM and YSI, the difference, absolute difference, relative difference and absolute relative difference is calculated. The biases for all three doses are calculated by subtracting the baseline bias at pre-dose from the post-dose bias as shown in the ‘Difference from Baseline’ column below.

Time Interval (Hour) Relative to Dose	Difference (Bias, mg/dL)				Relative Difference (%)			
	Difference from Baseline	Mean	Median	SD	Difference from Baseline	Mean	Median	SD
Pre-dose (0)	0.0	-2.4	-2.3	13.5	0.0	-1.7	-1.6	9.05
Post 1st dose: 0-1 hour (1)	-2.9	-5.3	-3.3	14.3	-1.8	-3.5	-2.7	10.2
Post 1st dose: 1-2 hour (2)	5.4	2.9	3.0	17.0	3.8	2.1	1.5	12.4
Post 1st dose: 2-3 hour (3)	9.3	6.9	5.6	15.4	6.2	4.5	3.8	11.1
Post 1st dose: 3-4 hour (4)	8.7	6.2	5.8	13.5	5.9	4.2	4.1	9.96
Post 2nd dose: 0-1 hour (5)	12.4	10.0	9.0	14.2	9.2	7.5	6.7	10.9
Post 2nd dose: 1-2 hour (6)	16.6	14.1	13.0	15.2	11.7	9.9	9.7	11.5
Post 2nd dose: 2-3 hour (7)	18.4	15.9	15.5	16.2	12.8	11.1	9.9	12.0
Post 2nd dose: 3-4 hour (8)	14.9	12.4	12.8	13.7	9.9	8.2	7.9	11.1
Post 3rd dose: 0-1 hour (9)	14.5	12.1	12.3	15.9	9.2	7.5	8.0	11.3
Post 3rd dose: 1-2 hour (10)	18.9	16.5	17.8	17.7	11.6	9.9	10.5	12.1
Post 3rd dose: 2-3 hour (11)	19.7	17.3	16.3	19.0	12.8	11.1	12.0	13.1
Post 3rd dose: 3-4 hour (12)	19.0	16.5	16.0	17.9	12.8	11.1	10.5	13.4

The figure below shows the mean bias from the baseline at different time points. The results show that the maximum bias was observed at around 3 hours after the intake of each dose of vitamin C, with a maximum average bias of 9.3 mg/dL after the first 1000 mg dose. The maximum average biases were 18.4 mg/dL and 19.7 mg/dL after the second and third doses respectively.



Based on the results of the clinical evaluation, the following statements have been placed in the device labeling:

- 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.

- A clinical study was conducted to evaluate the effect of ascorbic acid on Sensor performance. Data from 57 adult subjects with diabetes was collected over a 13-hour period. Each subject had a one-hour baseline phase where venous blood was collected every 10 minutes. After this first hour, a dose of 1000 mg ascorbic acid was given with a meal and venous samples were collected every 20 minutes for the next four hours. A maximum average sensor bias of 9.3 mg/dL was observed around 3 hours after the 1000 mg ascorbic acid dose. Subjects then received a second dose of 1000 mg ascorbic acid with a meal and the same process was continued for another 4 hours. A third dose of 1000 mg ascorbic acid was then given and study subjects were followed for 4 more hours. After the second dose of ascorbic acid the maximum average sensor bias increased, with minimal change in sensor bias after the third dose, suggesting that saturation had occurred by the second 1000 mg dose of ascorbic acid. The maximum average sensor bias after the three 1000 mg doses of ascorbic acid was less than 20 mg/dL.

1.7.2 Comparison Studies

I. Method comparison with predicate device.

Not applicable

II. Matrix comparison:

Not applicable. Interstitial fluid is the only indicated matrix

1.7.3 Clinical Studies

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. SMBG was the comparator method used for pediatric subjects aged 4-5 years.

To demonstrate the accuracy performance of the FreeStyle Libre 2 Flash Glucose Monitoring System, two prospective clinical studies (Study 1, adult; Study 2, pediatric) were conducted at five and four centers, respectively. All study centers were located in the United States. Results from these studies are presented concurrently.

Study 1 enrolled 146 adult subjects with diabetes. Of these, 91.1% were diagnosed with Type 1 diabetes, while 8.9% were diagnosed with Type 2 diabetes. All subjects required insulin to manage their diabetes. Subjects wore 2 sensors for up to 14 days. Subjects took part in up to three ten-hour clinical sessions. Clinic sessions for each subject took place during four distinct periods: days 1, 2 and 3; days 7 and 8; days 9 and 12, and days 13 and 14. During each clinic session, each subject's glucose was manipulated to achieve sustained periods of either hypoglycemia or hyperglycemia, or both.

Study 2 enrolled 139 pediatric subjects with diabetes. Of these, 98.6% were diagnosed with Type 1 diabetes, while 1.4% with Type 2 diabetes. All subjects required insulin to manage their diabetes. Subjects wore 2 sensors for up to 14 days. Subjects age six and older took part in up to two eight-hour clinical sessions. No YSI comparator measurements were obtained for subjects 4-5 years of age, and performance for these subjects was compared against self-monitoring blood glucose (SMBG) tests. Clinic sessions for each subject took place during four distinct periods: days 1, 2 and 3; days 7 and 8; days 9 and 12, and days 13 and 14. During each clinic session, each subject's glucose was manipulated to achieve sustained periods of either hypoglycemia or hyperglycemia, or both.

In Study 1 and Study 2, accuracy of the FreeStyle Libre 2 Flash Glucose Monitoring System was evaluated by comparing iCGM glucose values to reference glucose values. 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.

Percent and Point Accuracy by iCGM Glucose Range (Study 1, Adult)

iCGM Glucose Range (mg/dL)	No. Pair	No. Subject	Percent within 15 mg/dL (95% LCL)	Percent within 40 mg/dL (95% LCL)	Percent within 15% (95% LCL)	Percent within 40% (95% LCL)
<70	3530	130	89.0 (86.7)	99.4 (99.1)		
70-180	7785	144			75.9 (73.1)	99.6 (99.4)
>180	7420	141			91.5 (89.4)	100.0 (99.9)

Percent and Point Accuracy by iCGM Glucose Range (Study 2, Pediatric*)

iCGM Glucose Range (mg/dL)	No. Pairs	No. Subject	Percent within 15 mg/dL (95% LCL)	Percent within 40 mg/dL (95% LCL)	Percent within 15% (95% LCL)	Percent within 40% (95% LCL)
<70	1002	77	82.7 (77.2)	98.6 (97.5)		
70-180	2690	124			78.0 (74.8)	99.3 (98.9)
>180	2854	124			87.3 (84.4)	99.7 (99.5)

* Results only include children 6-17 years of age with YSI measurement as comparator. SMBG measurements were obtained as comparator for children 4-5 years of age.

Percent and Point Accuracy by YSI Glucose Range (Study 1, Adult)

YSI Glucose Range (mg/dL)	No. Pair	No. Subject	Percent within 15 mg/dL (95% LCL)	Percent within 40 mg/dL (95% LCL)	Percent within 15% (95% LCL)	Percent within 40% (95% LCL)
<70	3468	130	95.3 (93.9)	100.0 (100.0)		
70-180	7504	144			76.5 (73.8)	99.6 (99.4)
>180	7763	141			88.9 (86.3)	99.9 (99.8)

Percent and Point Accuracy by YSI Glucose Range (Study 2, Pediatric*)

YSI Glucose Range (mg/dL)	No. Pairs	No. Subject	Percent within 15 mg/dL (95% LCL)	Percent within 40 mg/dL (95% LCL)	Percent within 15% (95% LCL)	Percent within 40% (95% LCL)
<70	882	67	94.9 (92.1)	100.0 (100.0)		
70-180	2743	124			75.6 (72.2)	99.0 (98.5)
>180	2921	122			87.7 (84.9)	99.1 (97.9)

* Results only include children 6-17 years of age with YSI measurement as comparator. SMBG measurements were obtained as comparator for children 4-5 years of age.

Percent values within 20% of the comparator method were calculated across the measuring range overall.

Percent of iCGM values within 20% of YSI reference

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)

*Only SMBG measurements were obtained as comparator for children 4-5 years of age

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.

Accuracy to YSI within CGM Glucose Ranges (Study 1, 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

Accuracy to YSI within CGM Glucose Ranges (Study 2, 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

* Results only include children 6-17 years of age with YSI measurement as comparator. SMBG measurements were obtained as comparator for children 4-5 years of age.

Accuracy to YSI within YSI Glucose Ranges (Study 1, Adult)

YSI 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 YSI within YSI Glucose Ranges (Study 2, Pediatric*)

YSI 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

* Results only include children 6-17 years of age with YSI measurement as comparator. SMBG measurements were obtained as comparator for children 4-5 years of age.

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 CGM Glucose Level (Study 1, Adult)

CGM (mg/dL)	YSI (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 CGM Glucose Level (Study 2, Pediatric*)

CGM (mg/dL)	YSI (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

* Results only include children 6-17 years of age with YSI measurement as comparator. SMBG measurements were obtained as comparator for children 4-5 years of age.

Concurrence Analysis by YSI Glucose Level (Study 1, Adult)

YSI (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 YSI Glucose Level (Study 2, Pediatric*)

YSI (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

* Results only include children 6-17 years of age with YSI measurement as comparator. SMBG measurements were obtained as comparator for children 4-5 years of age.

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 to <-2 mg/dL. Trend accuracy was assessed by the concurrence rate of the glucose rate of change (changes in mg/dL of glucose per minutes) determined by the iCGM trend arrow and the corresponding comparator values for each iCGM-comparator measurement pair.

Concurrence Analysis by Glucose Rate of Change (Study 1, Adult)

CGM (mg/dL/min)	YSI (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	46.5	41.2	4.0	0.9	0.6	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	0.1	0.2	3.1	14.6	32.9	49.0	881

Concurrence Analysis by Glucose Rate of Change (Study 2, Pediatric*)

CGM (mg/dL/min)	YSI (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

* Results only include children 6-17 years of age with YSI measurement as comparator. SMBG measurements were obtained as comparator 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 (Study 1: Adult)

CGM-Reference Pairs	YSI 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 (Study 2: Pediatric*)

CGM-Reference Pairs	YSI 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	

* Results only include children 6-17 years of age with YSI measurement as comparator. SMBG measurements were obtained as comparator for children 4-5 years of age.

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Concurrence Analysis with 'HI' CGM Reading (Study 1: Adult)

CGM-Reference Pairs	YSI 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 (Study 2: Pediatric*)

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

* Results only include children 6-17 years of age with YSI measurement as comparator. SMBG measurements were obtained as comparator for children 4-5 years of age.

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Alarm Performance

The tables in this section show the accuracy of the System's Low and High Glucose Alarms. The Alarm Rate tells you how often the alarm is right or wrong. The Detection Rate tells you how often the System recognizes and notifies you about a low or high glucose event.

Low Glucose Alarm Performance

True Alarm Rate
Tells you: When you got a low glucose alarm, were you actually low?
Definition: 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
Tells you: Did you get a low glucose alarm that you shouldn't have?
Definition: 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
Tells you: When you were low, did you get a low glucose alarm?
Definition: 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
Tells you: When you were low, did you miss a low glucose alarm?
Definition: 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.

For example, the Adult study found that for a Low Glucose alarm level set to 70 mg/dL:
86.0% of the time a low glucose alarm was received when blood glucose was below the alarm level but 14.0% of the time a low glucose alarm was received when blood glucose was not below the alarm level.

89.3% of the time blood glucose was below the alarm level and a low glucose alarm was appropriately issued but 10.7% of the time the glucose event was missed and no alarm was issued.

Low Glucose Alarm Performance (Adult)

Low Glucose Alarm level (mg/dL)	Alarm Rate			Detection Rate		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of 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		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of 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

* Results only include children 6-17 years of age with YSI measurement as comparator. SMBG measurements were obtained as comparator for children 4-5 years of age.

<u>High Glucose Alarm Performance</u>

True Alarm Rate
Tells you: When you got a high glucose alarm, were you actually high?
Definition: 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
Tells you: Did you get a high glucose alarm that you shouldn't have?
Definition: 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
Tells you: When you were high, did you get a high glucose alarm?
Definition: 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
Tells you: When you were high, did you miss a high glucose alarm?
Definition: 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.

For example, the Adult study found that for a High Glucose alarm level set to 200 mg/dL: 99.2% of the time a high glucose alarm was received when blood glucose was above the alarm level but 0.8% of the time a high glucose alarm was received when blood glucose was not above the alarm level.

97.1% of the time blood glucose was above the alarm level and a high glucose alarm was appropriately issued but 2.9% of the time the glucose event was missed and no alarm was issued.

High Glucose Alarm Performance (Adult)

High Glucose Alarm level (mg/dL)	Alarm Rate			Detection Rate		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of 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		
	Number of Events (n)	True Alarm Rate (%)	False Alarm Rate (%)	Number of 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	13559	98.0	2.0	2172	95.7	4.3
300	6064	90.8	9.2	962	91.0	9.0

* Results only include children 6-17 years of age with YSI measurement as comparator. SMBG measurements were obtained as comparator 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 percentage of FreeStyle Libre 2 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 at the beginning Adult: Days 1-3, Pediatric: Day 1-2) Early Middle (Adult: Days 7-8, Pediatric: Day 7-8), Late Middle (Adult: Days 9-12, Pediatric: Day 9-12), and End (Adult: Days 13-14, Pediatric: Day 13-14). The mean of the absolute relative differences was evaluated over 14 day life of the sensor within measuring range.

Sensor Accuracy Relative to YSI Comparator over the wear duration (Study 1: 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 YSI Comparator over the wear duration (Study 2: 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

* Results only include children 6-17 years of age with YSI measurement as comparator. SMBG measurements were obtained as comparator 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. 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. 3 Sensors (2.2%) 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.

Sensor Survival Rate Over Wear Duration (Study 1: 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 (Study 2: 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
10	124	89.9
11	122	88.4
12	120	87.0
13	114	83.4
14	104	78.1

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 (Study 1: 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 (Study 2: 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
10	125	95.6
11	125	95.6
12	122	95.8
13	119	95.9
14	116	95.8

1.7.4 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:

- FDA Guidance titled *Applying Human Factors and Usability Engineering to Medical Devices*, dated 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

1.7.5 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.

1.7.6 Biocompatibility

Biocompatibility testing in accordance with ISO10993-1and 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.

1.7.7 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 met the acceptance criteria and supports sterility of the patient contact components of the device.

1.7.8 Shelf-Life and Stability

Sensor Kit shelf life stability testing provided objective evidence to support a shelf life of 9 months. The testing conducted satisfied specifications. 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.

1.7.9 Packaging Integrity/Shipping Integrity

Packaging and shipping integrity testing was performed for 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.

1.7.10 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).

1.7.11 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.

1.7.12 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.

1.7.13 Test Strip Claim Support

The FreeStyle Precision Neo Blood Glucose Test Strips cleared under K171941 are compatible for use with the FreeStyle Libre 2 built-in meter for quantitative measurement of glucose from fresh capillary whole blood drawn from fingertips. Studies to support the use of the FreeStyle Libre 2 Reader's built-in meter with the FreeStyle Precision Neo Blood Glucose Test Strips (K171941) demonstrated that all acceptance criteria were met as defined by specification.

1.7.14 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).

1.7.15 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. Appropriate risk mitigation controls have been implemented and tested.

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

1.8 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.

1.9 Conclusion

The FreeStyle Libre 2 Flash Glucose Monitoring System has the same intended use and clinical application as the predicate device. There are no differences in technological characteristics that raise questions of safety or effectiveness. The FreeStyle Libre 2 System provides significant benefits to users (including glucose readings, trends, real time alerts, a short sensor warm-up period, factory calibration, and the ability to autonomously communicate with digitally connected devices where the user manually controls actions for therapy decisions) that outweigh any potential risks associated with iCGM technology. Clinical studies in adult and pediatric patients have demonstrated that the FreeStyle Libre 2 System provides accurate and reliable glucose readings in accordance with the iCGM special controls relating to accuracy and does not post any clinically significant risks not seen with the predicate device. Accordingly, based on this and the data provided in this pre-market notification, the subject device and predicate device have been shown to be substantially equivalent.