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

I Background Information:

A 510(k) Number

K211102

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:

Modification of the cleared device to add compatibility with the 10-day MediRx sensor.

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.

The System can be used with the FreeStyle Libre 2 Sensor (14 day) or the FreeStyle Libre 2 MediRx Sensor (10 day).

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

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

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

The System must be removed prior to Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The effect of MRI, CT scans, or diathermy on the performance of the System has not been evaluated. The exposure may damage the Sensor and may impact proper function of the device which could cause incorrect readings.

Do not use this system if you are pregnant, on dialysis, or critically ill. The System is not cleared for use in these groups and it is not known how different conditions or medications common to these populations may affect performance of the System.
Do not ignore symptoms that may be due to low or high blood glucose: if you are experiencing symptoms that are not consistent with the glucose readings, consult your health care professional.

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

Use your blood glucose meter to make diabetes treatment decisions when you see the "check blood glucose" symbol during the first 12 hours or wearing a Sensor. In addition, use your blood glucose meter to make diabetes treatment decisions, if your Sensor glucose reading does not match how you feel, or if the reading does not include a number.
Wash application site on the back of your upper arm using a plain soap, dry, and then 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 health care professional.

D Special Instrument Requirements:
Not applicable.

IV Device/System Characteristics:

A Device Description:
The FreeStyle Libre 2 Flash Glucose Monitoring System is an integrated continuous glucose monitoring (iCGM) system that provides continuous glucose measurements every minute to provide glucose levels, trends, and real-time alarms capability to aid in the management of diabetes. 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 radiofrequency identification (RFID) scanning of the Sensor via Reader provides the user with real-time glucose measurements (glucose values) accompanied by trend information (glucose arrows) and historical glucose information (glucose graph). Users may use the Sensor glucose results and information provided by the System in making treatment decisions. The System also provides configurable alarms designed to warn the user of Low Glucose, High

Glucose or Signal Loss. The system is intended for single-patient use at home and requires a prescription.

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 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 and does not require fingerstick calibration.

FreeStyle Libre 2 Reader

- The Reader is a small handheld device that is powered by a lithium-ion rechargeable battery and uses RFID communication to start new Sensors and to scan Sensors to display and record data and uses blue tooth low energy BLE communication to issue alarms that notify the user to scan his/her sensor when glucose values pass a high or low glucose threshold. The Reader also has a built-in strip port with blood glucose functionality (that is intended to work with the FreeStyle Precision Neo Blood Glucose test strips, cleared under K171941), and a user interface that includes event logging features.

The FreeStyle Libre 2 MediRx Sensor with a 10-day wear duration is an alternate configuration to the existing FreeStyle Libre 2 Sensor, which has a 14-day wear duration. The FreeStyle Libre 2 MediRx Sensor design is unchanged from that of the predicate Sensor (the FreeStyle Libre 2 Flash Glucose Monitoring System). The algorithm and Reader design in the FreeStyle Libre 2 MediRx Sensor are also the same as those of the predicate.

As with the predicate, the System is intended to be used when the user utilizes CGM information to manually control actions for therapy decisions. The System must not be used with automated insulin dosing (AID) systems, which include 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 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.

C Instrument Description Information:

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

2. Specimen Identification:
   Not applicable.

3. Specimen Sampling and Handling:
   Not applicable.

4. Calibration:
   The device is factory calibrated and does not require calibration from the user/operator.

5. Quality Control:
   Not applicable.

V Substantial Equivalence Information:

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

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

C Comparison with Predicate(s):

Device & Predicate Device(s):	K211102	K193371
Device Trade Name	FreeStyle Libre 2 Flash Glucose Monitoring System	FreeStyle Libre 2 Flash Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use/Indications For Use	The FreeStyle Libre 2 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real-time alarm capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose (BG) 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	Same

Device & Predicate Device(s):	K211102	K193371
	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.	
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
Test Range	40 to 400 mg/dL	Same
Clinical Setting/Sites of Use	Home Setting	Same
Data Displayed	Current glucose value, current glucose trend, graph with recent glucose history, user-entered events	Same
Primary Display Device	FreeStyle Libre 2 Reader	Same
Alerts and Alarms	Low Glucose Alarm, High Glucose Alarm, Signal Loss Alarm, Scan Error, Sensor Error	Same
Wireless Communication Protocol	Near Field Communication (NFC): (13.56 MHz RFID) Bluetooth Low Energy (BLE): 4.0	Same
BLE Communication	20 feet unobstructed	Same
Sensor Glucose Algorithm	FreeStyle Libre 2 Reader Algorithm	Same
Method of Sensor Activation	RFID Communication	Same
Method of Data Transfer from Sensor	RFID – upon user-initiated scan BLE – for glucose data to support glucose alarms	Same
Glucose Reading Update Interval	Every 1 minute	Same

Device & Predicate Device(s):	K211102	K193371
Trend Graph Glucose History	8 hours, 24-hour graph and other reports can be used to view logged data	Same
Sensor Calibration	Factory calibrated	Same
Anatomical Sensor Wear Locations	Back of upper arm	Same
Sensor Warm-up Time	1 hour	Same
General Device Characteristic Differences		
Compatible Sensors	FreeStyle Libre 2 Sensor (14-day), or FreeStyle Libre 2 MediRx Sensor (10-day)	FreeStyle Libre 2 Sensor (14-day)
Retail Packaging Configuration for FreeStyle Libre 2 MediRx Sensor Kits	Two (2) packaging configuration options: • One (1) Sensor Kit carton with no additional outer carton • Three (3) individual Sensor Kit cartons packaged within an outer carton	N/A

VI Standards/Guidance Documents Referenced:

- FDA Guidance document *Applying Human Factors and Usability Engineering to Medical Dev*ices (February 3, 2016)
- ISO 14971: 2019 – "Medical Devices-Application of Risk Management to Medical Devices"
- ANSI AAMI IEC 62304:2006/A1:2016 - "Medical device software - Software life cycle processes"
- AAMI/IEC 62366-1:2015 -"Medical Devices-Application of Usability Engineering to Medical Devices"
- AAMI/ANSI HE75: 2009/(R)2018 -"Human Factors Engineering -Design of Medical Devices"

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision of the System with the FreeStyle Libre 2 sensor (14 day) was previously established in K193371. Precision data was reanalyzed for the proposed 10-day wear period of the FreeStyle Libre 2 MediRx sensor and presented in the tables below.

For adults (18 years and older), the paired absolute relative difference (PARD) between the two sensors was 8.2% with mean coefficient of variation (CV) of 5.8%. For children ages 4-5, PARD was 6.9% with mean CV of 4.9%. For children ages 6-17, PARD was 8.0% with CV of 5.7%.

Overall between Sensor Precision (Adult; n=146)

	Mean Coefficient of Variation (%)	Paired Absolute Difference (mg/dL)	Paired Absolute Relative Difference (%)	Number of Paired Readings
Adults ages 18+	5.8	12.6	8.2	20524

Overall between Sensor Precision (Pediatric; n=137)

	Mean Coefficient of Variation (%)	Paired Absolute Difference (mg/dL)	Paired Absolute Relative Difference (%)	Number of Paired Readings
Children ages 4-5	4.9	11.0	6.9	209
Children ages 6-17	5.7	12.8	8.0	7797

2. Linearity:
   See Section A(4), Assay Reportable Range below

3. Analytical Specificity/Interference:
   For this device and the predicate, ascorbic acid (vitamin C) has been shown to significantly interfere with system performance. Analytical Specificity/Interference was previously assessed in K193371.

   Based on the results of the clinical evaluation and bench testing for ascorbic acid, the following statements have been placed in the device labeling:

   - 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.

4. Assay Reportable Range:
   The Assay Reportable Range was previously assessed in K193371. The reportable range for the System with the FreeStyle Libre 2 MediRx Sensor remains unchanged as 40 to 400 mg/dL.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
   The shelf-life of the FreeStyle Libre 2 sensor was previously evaluated in K193371. Both the FreeStyle Libre 2 sensor and FreeStyle Libre 2 MediRx sensor have 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'.

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 glucose measurement method and was previously assessed in K193371.

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):
   Two prospective clinical studies were conducted in the United States to support clearance of the predicate device in K193371.

   In both studies, accuracy of the FreeStyle Libre 2 sensor was evaluated by comparing iCGM glucose values to an FDA-cleared laboratory grade comparator method (CM, using the YSI 2300). Glucose values were obtained from the iCGM and from the comparator at the same or similar time. The accuracy of iCGM glucose versus the comparator method was assessed by

calculating the percentage of iCGM readings that were within 15%, 20%, and 40% for reference values ≥70 mg/dL, and within 15 mg/dL, 20 mg/dL, and 40 mg/dL for values < 70 mg/dL. For glucose values < 70 mg/dL, the difference in mg/dL between the CGM and comparator glucose values was calculated. For values ≥70 mg/dL, the relative difference (%) to the comparator value was calculated.

The study data was reanalyzed to include data from the first 10 days of sensor wear, to align with the proposed intended use of the System with the FreeStyle Libre 2 MediRx Sensor. The sponsor did not collect paired glucose data on Day 10 due to the clinic visit schedule for both studies. Therefore, paired CGM-CM data up to Day 9 are presented in the tables below. Assessment of Day 12 data (where paired CGM-CM data are available) indicates that the performance data below is representative of the device performance for 10 days of wear.

Percent and Point Accuracy by iCGM Glucose Range (Adult)

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	2550	88.1 (85.9)	99.2 (98.8)			-4.0 (-3.0)
70-180	5340			75.9 (72.9)	99.6 (99.4)	-6.7 (-5.0)
>180	5444			92.2 (90.3)	99.9 (99.9)	-5.7 (-3.2)

*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	689	83.3 (77.6)	98.4 (96.9)			-6.6 (-4.2)
70-180	1721			77.6 (74.2)	99.4 (98.9)	-4.4 (-2.1)
>180	1949			90.6 (88.0)	99.7 (99.3)	-1.9 (1.5)

*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. 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	2344	94.6 (92.7)	100.0 (100.0)			0.6 (1.5)
70-180	5295			76.4 (73.6)	99.5 (99.3)	-5.3 (-3.9)
>180	5695			89.7 (87.5)	99.9 (99.8)	-8.1 (-5.5)

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	553	96.0 (93.4)	100.0 (100.0)			1.1 (2.3)
70-180	1821			74.0 (70.3)	99.0 (98.4)	-2.8 (-1.0)
>180	1985			89.9 (87.1)	99.4 (98.4)	-5.0 (-1.3)

*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)	13334	144	90.2 (88.7)
Pediatric (6-17 years)	4359	106	90.5 (88.2)
Pediatric (4-5 years old)*	267	8	83.5 (78.1)

*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 Range (Adults)

iCGM 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	411	84.7	93.2	99.3				-6.6	13.8
54-69	2139	88.7	93.6	98.8				-4.4	11.1
70-180	5340				75.9	86.4	99.1	-5.9	10.8
181-250	2202				88.8	94.7	99.9	-9.9	7.8
>250	3242				94.4	98.1	100.0	-4.9	6.1

Accuracy to Comparator within iCGM Glucose Ranges (Pediatric)

iCGM 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	109	71.6	77.1	96.3				-9.7	17.0
54-69	580	85.5	89.3	96.2				-5.8	11.7
70-180	1721				77.6	87.6	98.6	-4.7	10.6
181-250	787				86.0	93.6	99.5	-7.1	8.1
>250	1162				93.7	98.4	99.7	-1.8	6.9

Accuracy to Comparator within Comparator Glucose Range (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	285	93.7	98.9	100.0				6.7	14.0
54-69	2059	94.7	98.7	100.0				0.5	10.1
70-180	5295				76.4	86.4	99.2	-5.4	10.8
181-250	2138				86.6	93.1	99.5	-8.2	8.3
>250	3557				91.5	96.1	99.6	-10.7	6.9

Accuracy to Comparator within Comparator Glucose Range (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	93	94.6	97.8	100.0				6.6	13.9
54-69	460	96.3	99.1	100.0				0.1	8.1
70-180	1821				74.0	84.7	97.6	-4.1	11.6
181-250	743				86.8	92.2	98.7	-3.3	8.4
>250	1242				91.7	97.3	99.9	-8.9	7.3

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)

iCGM (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	0.3	51.4	44.2	3.9	.	0.1	.	.	.	.	.	1458
61-80	.	16.7	61.0	21.8	0.5	0.0	.	.	.	.	.	2036
81-120	.	0.0	10.2	70.0	18.6	1.0	0.1	.	.	.	.	2147
121-160	.	.	0.1	8.7	68.6	19.9	2.0	0.4	0.3	.	.	1617
161-200	.	.	.	.	11.1	59.8	26.9	1.8	0.4	.	.	1246
201-250	.	.	.	.	.	7.5	65.6	24.8	2.0	0.1	.	1588
251-300	.	.	.	.	.	0.1	8.7	67.9	21.7	1.4	0.1	1670
301-350	.	.	.	.	.	.	0.5	14.4	68.7	14.9	1.5	1121
351-400	.	.	.	.	.	.	.	0.7	27.5	62.3	9.5	451
>400†	.	.	.	.	.	.	.	.	2.7	65.5	31.8	110

Concurrence Analysis by iCGM Glucose Level (Pediatric)

iCGM (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	53.4	35.9	9.2	0.9	.	.	.	.	.	.	348
61-80	.	8.9	62.3	27.0	1.8	.	.	.	.	.	.	604
81-120	.	0.2	9.7	66.5	21.8	1.7	0.2	.	.	.	.	632
121-160	.	.	.	10.0	72.8	15.0	2.2	.	.	.	.	588
161-200	.	.	.	0.2	17.7	62.0	19.7	0.4	.	.	.	463
201-250	.	.	.	.	0.4	9.4	60.1	28.6	1.2	0.2	.	562
251-300	.	.	.	.	.	0.2	14.8	62.4	21.4	1.2	.	593
301-350	.	.	.	.	.	.	.	26.4	59.5	13.9	0.2	439
351-400	.	.	.	.	.	1.5	.	0.8	33.1	58.5	6.2	130
>400	.	.	.	.	.	.	.	6.9	6.9	31.0	55.2	29

Concurrence Analysis by Comparator Glucose Level (Adult)

CM Glucose Level (mg/dL)	iCGM (mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400	
<40	16.7	83.3	.	.	.	.	.	.	.	.	.	6
40-60	0.1	68.7	31.1	0.1	.	.	.	.	.	.	.	1091
61-80	0.1	30.6	58.9	10.4	0.0	.	.	.	.	.	.	2108
81-120	0.0	2.7	20.7	70.1	6.5	.	.	.	.	.	.	2145
121-160	.	.	0.7	24.1	66.9	8.3	.	.	.	.	.	1657
161-200	.	0.1	0.1	1.8	26.6	61.5	9.8	0.2	.	.	.	1212
201-250	.	.	.	0.2	2.1	21.4	66.6	9.3	0.4	.	.	1563
251-300	.	.	.	.	0.4	1.3	22.9	65.9	9.3	0.2	.	1722
301-350	.	.	.	.	0.4	0.4	2.5	27.9	59.1	9.5	0.2	1302
351-400	.	.	.	.	.	.	0.4	4.4	30.6	51.5	13.2	546
>400	.	.	.	.	.	.	.	2.1	17.5	44.3	36.1	97

Concurrence Analysis by Comparator Glucose Level (Pediatric)

CM Glucose Level (mg/dL)	iCGM Glucose Level (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		.	.	.	.	.	.	.	.	2
40-60	0.4	76.9	22.3	0.4	.	.	.	.	.	.	.	242
61-80	0.2	22.2	66.8	10.8	.	.	.	.	.	.	.	563
81-120	.	4.7	24.1	62.2	8.7	0.1	.	.	.	.	.	675
121-160	.	0.5	1.7	20.8	64.5	12.3	0.3	.	.	.	.	664
161-200	.	.	.	2.5	19.9	64.9	12.0	0.2	.	0.5	.	442
201-250	.	.	.	0.2	2.4	17.1	63.7	16.6	.	.	.	531
251-300	.	.	.	.	.	0.3	24.7	56.7	17.8	0.2	0.3	652
301-350	.	.	.	.	.	.	1.6	28.9	59.3	9.8	0.5	440
351-400	.	.	.	.	.	.	0.6	4.5	39.6	49.4	5.8	154
>400	.	.	.	.	.	.	.	.	4.0	32.0	64.0	25

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 Change (mg/dL/min)	CM Rate Change (mg/dL/min)						N
	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2	
<-2	33.3	46.0	18.0	2.3	0.4	--	261
[-2 to -1)	6.6	44.6	42.8	4.3	1.1	0.6	807
[-1 to 0)	1.2	8.5	66.8	19.6	2.7	1.2	6538
[0 to 1]	1.0	3.3	26.1	46.9	15.8	6.9	3879
(1 to 2]	--	1.7	7.2	32.0	39.9	19.3	838
>2	0.3	0.3	3.5	15.4	32.9	47.7	663

Concurrence Analysis by Glucose Rate of Change (Pediatric)

CGM Rate Change (mg/dL/min)	CM Rate Change (mg/dL/min)						N
	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2	
<-2	40.2	46.5	10.2	3.1	--	--	127
[-2 to -1)	11.3	47.9	35.1	5.2	0.3	0.3	328
[-1 to 0)	2.3	11.5	59.6	21.1	3.9	1.6	1633
[0 to 1)	1.3	5.8	24.9	43.0	14.3	10.7	1416
(1 to 2]	0.3	2.9	10.9	29.5	35.2	21.2	349
>2	--	0.6	4.4	15.4	30.5	49.1	318

Agreement when iCGM Reads 'LO' or 'HI'

The System reports glucose readings between 40 and 400 mg/dL. When the System determines that glucose level is below 40 mg/dL, it will display 'LO' whenever the sensor is scanned. When the System determines that glucose level 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' iCGM Reading (Adult)

iCGM-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' iCGM Reading (Pediatric*)

iCGM-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' iCGM Reading (Adult)

iCGM-Reference Pairs	Comparator (mg/dL)				N
	>350	>300	>250	>250	
n	107	110	110	0	110
Cumulative %	97.3	100.0	100.0	0.0	

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

iCGM-Reference Pairs	Comparator (mg/dL)				N
	>350	>300	>250	>250	
n	25	27	29	0	29
Cumulative %	86.2	93.1	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	7585	72.5	27.5	1045	81.4	18.6
70	15776	84.8	15.2	2468	90.5	9.5
80	23510	89.7	10.3	3247	97.7	2.3
90	29792	92.5	7.5	3883	98.7	1.3

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	1879	67.9	32.1	247	96.0	4.0
70	4540	77.8	22.2	609	97.2	2.8
80	6697	84.7	15.3	835	97.7	2.3
90	8431	92.2	7.8	1061	98.2	1.8

* Includes children 6-17 years of age. No CM 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: Percentage 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; n=144)

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	75744	99.2	0.8	8527	98.1	1/9
140	67834	99.2	0.8	7382	98.1	1.9
180	54571	99.1	0.9	5950	97.8	2.2

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 (%)
200	48663	99.2	0.8	5368	97.0	3.0
220	42372	98.9	1.1	4718	96.9	3.1
240	36198	98.6	1.4	4115	95.6	4.4
300	16638	96.1	3.9	2009	90.9	9.1

High Glucose Alarm Performance (Pediatric*; n=106)

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	23261	98.9	1.1	3035	97.9	2.1
140	20458	98.5	1.5	2701	98.0	2.0
180	15409	98.5	1.5	2123	98.0	2.0
200	13321	98.3	1.7	1907	98.1	1.9
220	11246	97.8	2.2	1690	96.9	3.1
240	9325	98.6	1.4	1484	96.1	3.9
300	4198	89.8	10.2	657	92.7	7.3

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

Sensor Accuracy Over Time

Sensor accuracy over time (sensor stability) describes the performance of the sensor over the sensor lifetime. The FreeStyle Libre 2 MediRx sensor can be worn for up to 10 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 40% (40/40%) of the comparator values during the beginning, middle, and end of the wear period. These times were defined as follows:

- Beginning (Adult Days 1-3, Pediatric: Days 1-2)
- Middle (Adult: Days 7-8, Pediatric: Days 7-8),
- End (Adult: Day 9, Pediatric: Day 9).

The mean absolute relative difference (MARD) and agreement rates with the comparator method were evaluated over 10-day life of the sensor.

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

Sensor 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
Middle	4522	8.5	87.7	94.5	99.8
End	1857	9.0	86.4	93.8	99.6

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

Day	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
Middle	1642	8.0	89.5	94.2	98.5
End	889	9.8	82.9	92.1	99.4

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

Sensor Life

To estimate how long a Sensor will work for the 10-day wear duration, 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. Subjects did not wash the insertion site with soap and water before applying the Sensors and wore two Sensors simultaneously. Of the 146 Sensors in the Adult study, 82.2% lasted 10 days. In the Pediatric study, 89.9% of the Sensors lasted 10 days.

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	91.8
6	133	91.1
7	132	90.4
8	127	87.0
9	123	84.9
10	119	82.2

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
10	124	89.9

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. A total of 39 Sensors were evaluated in this study, all the Sensors (100%) lasted 10 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

Glucose Reading Capture Rate Over Wear Duration (Pediatric)

Day of Wear	Number of Sensors	Capture Rate (%)
1	139	94.6
2	137	94.9
3	136	95.2
4	133	95.3
5	134	95.5

Day of Wear	Number of Sensors	Capture Rate (%)
6	133	95.6
7	133	96.0
8	133	95.9
9	130	95.7
10	125	95.6

D Clinical Cut-Off:
Not applicable.

E Expected Values/Reference Range:
Not applicable.

F Other Supportive Instrument Performance Characteristics Data:

The FreeStyle Libre 2 Flash Glucose Monitoring System, when used with the FreeStyle Libre 2 MediRx Sensor, is identical to the predicate except for the sensor wear period. The following tests for the predicate device are leveraged in this 510(k):

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

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.