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

I Background Information:

A 510(k) Number

K233655

B Applicant

Abbott Diabetes Care Inc.

C Proprietary and Established Names

Lingo Glucose System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
SAF	Class II	21 CFR 862.1355 - Integrated Continuous Glucose Monitoring System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Glucose from 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 Lingo Glucose System is an over-the-counter (OTC) integrated Continuous Glucose Monitor (iCGM) intended to continuously measure, record, analyze and display glucose values in people 18 years and older not on insulin. The Lingo Glucose System helps to detect euglycemic and dysglycemic glucose levels. The Lingo Glucose System may also help the user better understand how lifestyle and behavior modification, including diet and exercise, impact glucose excursion.

The user is not intended to take medical action based on the device output without consultation with a qualified healthcare professional.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

Do not use the Lingo Biosensor if you are on dialysis or critically ill. It is not known how different conditions or medications common to these populations may affect performance of the System.

Only apply the Lingo Biosensor to the back of the upper arm. If placed in other areas, the Lingo Biosensor may not function properly.

Taking more than 1000 mg of Vitamin C per day may falsely raise your Lingo Biosensor readings. Vitamin C can be found in supplements including multivitamins and cold remedies such as Airborne® and Emergen-C®. See your health care professional to understand how long Vitamin C is active in your body.

D Special Instrument Requirements:

Not applicable

IV Device/System Characteristics:

A Device Description:

The Lingo Glucose System is a home use device that is intended to continuously measure the glucose in the interstitial fluid, calculate the glucose reading and make this value available to the user. The Lingo System can reliably and securely transmit glucose measurement data to authorized digitally connected devices. The system is not intended to be used in conjunction with insulin devices such as insulin pens and Automated Insulin Dosing (AID) systems. The Lingo Glucose System includes the Lingo Glucose Biosensor and the Lingo App.

<u>Lingo Biosensor</u>

The Lingo Glucose Biosensor hardware and technology is based on the FDA-cleared FreeStyle Libre 2 (FSL2) sensor (K222447). The Biosensor is a single use disposable on-body Biosensor

that incorporates a subcutaneously implanted electrochemical glucose sensor and associated electronics. The Biosensor can be worn for up for 14 days and transmits data to the Lingo App via Bluetooth Low Energy (BLE).

Lingo App (iOS)
The Lingo App is designed to work in conjunction with the Lingo Glucose Biosensor. The Lingo App, which is the primary display for the Lingo System, operates on an iOS-compatible mobile device and can be downloaded from the Apple App Store.

B Principle of Operation:

The Lingo Glucose 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 an electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the ISF. The system converts the electrical current signal to a glucose value (in mg/dL) for display to the user on a display device.

C Instrument Description Information:

1. Instrument Name:

   Lingo Glucose System

2. Specimen Identification:

   Not applicable

3. Specimen Sampling and Handling:

   Not applicable

4. Calibration:

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

5. Quality Control:

   Not applicable

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

V Substantial Equivalence Information:

A Predicate Device Name(s):

FreeStyle Libre 2 Flash Glucose Monitoring System

B Predicate 510(k) Number(s):

K222447

C Comparison with Predicate(s):

Device & Predicate Device(s):	K233655	K222447
Device Trade Name	Lingo Glucose System	FreeStyle Libre 2 Flash Glucose Monitoring System
General Device Characteristic Similarities		
Intended Use	Automatically measure glucose in bodily fluids continuously for a specified period of time.	Same
Principle of operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction.	Same
General Device Characteristic Differences		
Intended Use Population	Persons 18 years and older not on insulin	Persons with diabetes age 2 years and older
Availability to user	Over the counter	Prescription use only
Glucose Measuring Range	55 to 200 mg/dL	40 to 400 mg/dL
Device features to manage diabetes	None	Alarms, glucose trend arrows, interoperability
Wear period	14 days	15 days

VI Standards/Guidance Documents Referenced:

- 21 CFR 862.1355 (integrated continuous glucose monitoring system (iCGM)) special controls
- ISO14971- 2019-12 "Medical Devices-Application of Risk Management to Medical Devices"
- IEC 62304 -"Medical Device Software-Software Life Cycle Processes"
- IEC 60601-1-"Medical Electrical Equipment -Part 1: General Requirements for Basic Safety and Essential Performance"
- AAMI TIR69-"Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems"
- AAMI TIR57: 2016- "Principles for medical device security – Risk management"
- IEC 60601-1-2-"Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests"
- ISO 15223-1-"Medical Device-Symbols to be used with Medical Device Labels, Labeling and Information to be Supplied-Part 1: General Requirements"

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

iCGM performance was evaluated using leveraged clinical studies from the predicate as the sensor component is identical. A new statistical analysis was performed to account for the different age range (predicate device is 2 years and older; subject device is 18 years and older), the truncated glucose measuring range (predicate device is 40 – 400 mg/dL; subject device is 55 – 200 mg/dL) and the shortened wear period (predicate device is 15 days; subject device is 14 days).

1. Precision/Reproducibility:

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

In the study for all users, the mean paired absolute relative difference (between the 2 concurrently worn devices) was 8.4 %; and the median coefficient of variation (median %CV) was 4.2 %; mean %CV was 5.9%.

Precision Analysis

Glucose Level (mg/dL)	Mean Coefficient of Variation (%)	Paired Absolute Difference (mg/dL)	Paired Absolute Relative Difference (%)	Number of Paired Readings	Number of Subjects
All	5.9	9.2	8.4	14202	148

2. Linearity:

   See assay Reportable Range below.

3. Analytical Specificity/Interference:

   Previously established in K222447.

4. Assay Reportable Range:

   The reportable range for the Lingo Glucose Monitoring System is 55 to 200 mg/dL.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   The storage shelf-life of 9 months at 36 to 82 °F within the humidity range of 10 % - 90 % previously established for the predicate in K222447 is applicable to the subject device.

6. Detection Limit:

   Not applicable

7. Assay Cut-Off:

   Not applicable

8. Accuracy (Instrument):

   Not applicable

9. Carry-Over:

   Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable. Accuracy is determined by comparing device values to an FDA cleared laboratory grade glucose measurement method.

2. Matrix Comparison:

   Not applicable. Interstitial fluid is the only indicated matrix.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

The clinical data of the predicate FreeStyle Libre 2 Flash Glucose Monitoring System (K222447) was reanalyzed to support the Lingo Glucose System.

The accuracy performance was assessed in a single pivotal clinical study conducted in the United States at seven centers.

The study enrolled 150 adult subjects with diabetes. Subjects wore two sensors for up to 16 consecutive days following Sensor application and accuracy analysis is based on the first applied sensor to each subject only. Subjects took part in up to three ten-hour clinical sessions that took place during four distinct periods: Days 1 to 3; Days 5 to 7; Days 9 to 11, and Days 13 to 15. During each clinic session, each subject's glucose was manipulated to observe data spanning the measuring range. Data from day 15 of wear are not considered in the following analyses.

Device accuracy was evaluated by comparing iCGM glucose values to glucose values from venous blood draws measured with an FDA-cleared laboratory grade comparator method (YSI 2300). Glucose values were obtained from the system and from the comparator at the same or similar time. Glucose values outside of the subject device measuring range are not included in the following analysis. 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

iCGM Glucose Range (mg/dL)	No. Pairs	No. Subjects	Within 15 mg/dL (95% LB)	Within 40 mg/dL (95% LB)	Within 15% (95% LB)	Within 40% (95% LB)	Mean Bias (mg/dL)	MARD (%)
< 70 (55-69)	2765	128	91.5 (89.4)	99.6 (99.3)			-4.0	9.9
70 – 180	7513	148			82.1 (79.7)	99.6 (99.4)	-6.3	9.7
>180 (181-200)	808	138			86.5 (83.0)	99.9 (99.4)	-9.0	8.1

Percent and Point Accuracy by Comparator Method (CM) Glucose Range

CM Glucose Range (mg/dL)	No. Pairs	No. Subjects	Within 15 mg/dL (95% LB)	Within 40 mg/dL (95% LB)	Within 15% (95% LB)	Within 40% (95% LB)	Mean Bias (mg/dL)	MARD (%)
< 70 (55-69)	2386	120	96.9 (95.5)	99.9 (99.6)			1.4	8.9
70 – 180	7564	149			81.4 (79.0)	99.6 (99.5)	-5.8	9.7
>180 (181-200)	1136	135			77.5 (73.3)	99.4 (98.8)	-21.9	10.7

Percent of iCGM values within 20% of Comparator Glucose Values (N=149)

iCGM Glucose Range	Matched Pairs (n)	Percent within 20% (95% LCL)
55-200 mg/dL	11086	89.9 (88.0)

Concurrence

Concurrence of iCGM values compared to the comparator method across the entire measuring range was also evaluated. iCGM glucose ranges of <55, 55-70, 71-90, 91-120, 121-160, 161-200, and >200 mg/dL were evaluated against the comparator glucose ranges and the percentages of iCGM values within those ranges were reported in the following tables.

Concurrence of iCGM and Comparator by iCGM Glucose Range

	Comparator Glucose Values (mg/dL)							
iCGM (mg/dL)	**<55**	**55-70**	**71-90**	**91-120**	**121-160**	**161-200**	**>200**	**Total**
<55	39.5%	48.4%	9.9%	1.8%	0.1%	0.1%		706
55-70	8.4%	65.9%	23.4%	1.9%	0.4%			2913
71-90	0.4%	16.5%	52.5%	28.4%	2.3%	0.1%		1851
91-120		0.8%	7.4%	62.7%	27.2%	1.7%	0.1%	2200
121-160		0.0%	0.2%	6.4%	71.8%	20.0%	1.6%	2355
161-200				0.1%	9.8%	68.0%	22.1%	1767
>200					0.1%	2.4%	97.5%	7243

Concurrence of iCGM and Comparator by Comparator Glucose Range

	Comparator Glucose Values (mg/dL)						
iCGM (mg/dL)	**<55**	**55-70**	**71-90**	**91-120**	**121-160**	**161-200**	**>200**
<55	52.6%	13.2%	3.7%	0.6%	0.0%	0.1%	
55-70	46.0%	74.2%	36.1%	2.6%	0.4%		
71-90	1.3%	11.8%	51.3%	24.7%	1.7%	0.1%	
91-120		0.7%	8.6%	64.9%	23.8%	2.0%	0.0%
121-160		0.0%	0.3%	7.1%	67.1%	25.0%	0.5%
161-200				0.1%	6.9%	63.6%	5.2%
>200					0.2%	9.3%	94.3%
Total	530	2586	1892	2125	2521	1887	7494

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

iCGM Rate (mg/dL/min)	Comparator Rate (mg/dL/min)					
	<-2	**[-2, -1)**	**[-1, 0)**	**[0, 1]**	**(1, 2]**	**>2**
<-2	41 (48.2%)	61 (10.5%)	28 (0.5%)	5 (0.1%)	2 (0.2%)	1 (0.2%)
-2 to -1	22 (25.9%)	197 (33.8%)	166 (3.1%)	23 (0.7%)	5 (0.6%)	2 (0.4%)
-1 to 0	18 (21.2%)	280 (48.1%)	4294 (80.8%)	1261 (37.8%)	101 (11.2%)	52 (10.4%)
0 to 1	4 (4.7%)	43 (7.4%)	807 (15.2%)	1907 (57.1%)	486 (53.9%)	203 (40.5%)
1 to 2	0 (0%)	1 (0.2%)	13 (0.2%)	122 (3.7%)	205 (22.8%)	103 (20.6%)
>2	0 (0%)	0 (0%)	5 (0.1%)	21 (0.6%)	102 (11.3%)	140 (27.9%)
Number of Paired iCGM-Comparator (N)	85	582	5313	3339	901	501

Agreement when iCGM Reads "< 55 mg/dL" or "> 200 mg/dL"

The Lingo Glucose System reports glucose readings between 55 and 200 mg/dL. When the system determines the sensor reading is below 55 mg/dL, it displays "< 55 mg/dL" on the mobile app. When the system determines the sensor reading is above 200 mg/dL, it displays "> 200 mg/dL" on the mobile app. Because the system does not display glucose values below 55 mg/dL or above 200 mg/dL, the comparisons to the actual blood glucose levels (as determined by the comparator method) when the iCGM value is classified as "< 55 mg/dL" or " > 200 mg/dL" is evaluated separately, and the cumulative percentages of when the comparator values were less than certain glucose values (for "< 55 mg/dL") and when comparator values were greater than certain values (for "> 200 mg/dL") are presented in the tables below.

Distribution of Comparator for iCGM Readings "< 55 mg/dL"

iCGM Readings	CGM-Comparator Pairs	Comparator (mg/dL)				Total
		<70	<90	<120	≥120	
<55 mg/dL	N	621	691	704	2	706
	Cumulative %	88	97.9	99.7	0	

Distribution of Comparator for iCGM Readings "> 200 mg/dL"

iCGM Readings	CGM-Comparator Pairs	Comparator (mg/dL)						Total
		>180	>150	>120	>90	>70	≤70	
>200 mg/dL	n	7226	7241	7243	7243	7243	0	7243
	Cumulative %	99.8	100	100	100	100	0	

Sensor Stability

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

- Beginning (Days 1, 2 or 3)
- Early Middle (Days 5, 6 or 7),
- Late Middle (Days 9, 10 or 11), and
- End (Days 13 or 14).

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

Accuracy of iCGM vs Comparator by Wear Period

Wear Period	No. Pairs	MARD (%)	Within ±15% / ±15mg/dL	Within ±20% / ±20mg/dL	Within ±40% / ±40mg/dL
Beginning days (1-3)	3281	11.5	78.1	86.3	98.8
Early Middle days (5-7)	2896	8.5	87.0	93.9	99.7
Late Middle days (9-11)	2927	8.8	86.6	93.4	99.2
End days (13-14)	1982	9.2	87.2	92.3	99.3

Sensor Life

The sensor can be worn for up to 14 days. 151 Sensors were evaluated on the adult subjects to determine how many days of readings each Sensor provided.

Of the 151 sensors, 77.1% lasted until the final day of use. Some sensors were excluded from the analysis. For example, 4 sensors were intentionally removed due to subjects withdrawing or dropped out from the study early, one of which occurred during day 1 of the study. Of the sensors that did not last until the final day of use, 4 sensors (2.6%) had "early sensor shut-off" where the sensor algorithm detected that the sensor did not function as intended and automatically ended a sensor session. The Kaplan-Meier method was used to estimate how long a sensor will work over the wear duration.

Sensor Survival Rate Over Wear Duration

Day of Wear	No. of Sensors	Survival Rate (%)
1	150	100.0
2	150	100.0
3	149	99.3
4	147	98.0
5	142	94.7
6	139	93.3
7	138	92.7
8	131	88.0
9	129	86.6
10	127	85.3
11	125	83.9
12	122	81.9
13	118	79.9
14	111	77.1

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

Day of Wear	No. of Sensors	Capture Rate (%)
1	146	96.4
2	146	97.4
3	146	97.7
4	142	97.8
5	143	97.9
6	141	97.9
7	136	98.1
8	135	98.1
9	130	98.2
10	127	98.3
11	125	98.2
12	123	98.2
13	118	98.2
14	116	98.2

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable

F Other Supportive Instrument Performance Characteristics Data:

The following supportive performance characteristics were established through nonclinical testing of the predicate device and are applicable to the Lingo Glucose System:

- Biocompatibility
- Sterilization Validation
- Shelf Life

- Electrical and Mechanical Performance
- Operating Environmental Conditions Testing
- Wireless Coexistence
- Electrical Safety and Electromagnetic Compatibility
- Packaging Validation
- Interoperability

The following performance characteristics were verified or validated through studies conducted on the subject device, the Lingo Glucose System:

Electromagnetic Compatibility
Electromagnetic compatibility (EMC) testing was performed for the Lingo Glucose System to verify that the system is able to withstand the electromagnetic interference and emissions in compliance with IEC 60601-1-2 and IEC CISPR 11. Wireless coexistence testing was performed to confirm that the sensor remains 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*." The subject device underwent coexistence testing consistent with AAMI TIR69 and ANSI C63.27 and included test challenges from in-band interference sources defined in ANSI C63.27 as well as other expected wireless interference sources from the intended use environment. The Lingo Glucose System also successfully demonstrated compliance with Federal Communication Commission (FCC) Regulations Part 15.225 and Part 15.247, and Federal Aviation Administration (FAA) Advisory Circular RTCA DO-160.

Mechanical Engineering
The subject device underwent performance testing at the system level as well as on individual components of the Sensor Applicator. The test results showed that mechanical, electrical, and functional testing all met the acceptance criteria.

Software Verification and Validation

Software verification and validation testing was conducted in accordance with established specifications and IEC 62304 and documentation was provided as recommended by FDA Guidance "*Content of Premarket Submissions for Device Software Functions,*" issued June 14, 2023. Results of executed protocols met the acceptance criteria and therefore support that the sensor's embedded software and the Lingo App software are acceptable for its intended use.

Cybersecurity
Abbott has provided cybersecurity risk management documentation for the System that includes analysis of confidentiality, integrity, and availability for data, information and software related to the System accordance with FDA Guidance "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*," issued September 27, 2023. 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.

Human Factors
The user interface of the Lingo Glucose System has been found to support that the device is substantially equivalent to the predicate device for the intended users, uses, and use environments.

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.