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

I Background Information:

A 510(k) Number

K243214

B Applicant

Dexcom, Inc.

C Proprietary and Established Names

Dexcom G7 15 Day Continuous Glucose Monitoring System

D Regulatory Information

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

II Submission/Device Overview:

A Purpose for Submission:

Modifications to a cleared device to introduce a new glucose algorithm and to extend the wear period to 15 days for users 18 years and older.

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 Dexcom G7 15 Day Continuous Glucose Monitoring System (Dexcom G7 15 Day CGM System or G7 15 Day) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons 18 years and older.

The Dexcom G7 15 Day CGM System is intended to replace fingerstick BG testing for diabetes treatment decisions. Interpretation of the Dexcom G7 15 Day CGM System results should be based on the glucose trends and several sequential sensor readings over time. The Dexcom G7 15 Day CGM System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.

The Dexcom G7 15 Day CGM System is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. The Dexcom G7 15 Day CGM System can be used alone or in conjunction with these digitally connected medical devices for the purpose of managing diabetes.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

• Users of the Dexcom G7 15 Day Continuous Glucose Monitoring System can take a standard dose of acetaminophen (up to 1 gram every 6 hours in adults) and still use the Dexcom G7 15 Day CGM System readings. Sensor glucose readings will be falsely higher if the user is taking more than a standard acetaminophen dose.
• Sensor glucose readings will also be falsely higher if the user is taking hydroxyurea. Users should not use the Dexcom G7 15 Day CGM System for diabetes treatment decisions if they are taking hydroxyurea.
• Don't wear any Dexcom G7 15 Day CGM System component during magnetic resonance imaging (MRI) or high-frequency electrical heat (diathermy) treatment. However, it's safe to have a CT scan if you keep the sensor out of the scanned area and cover the sensor with a lead apron during the scan.
• Don't ignore low/high symptoms: Use BG meter to make treatment decisions when the sensor readings don't match the user's low/high symptoms. If needed, seek immediate medical attention.
• Use BG meter to make treatment decisions when the Dexcom G7 15 Day CGM System doesn't show both a number and trend arrow as well as during the sensor warmup period.
• Don't use if on dialysis or critically ill: The Dexcom G7 15 Day CGM System performance hasn't been evaluated in these populations and sensor readings may be inaccurate.
• Don't ignore broken or detached sensor wires. If this happens, contact 24/7 technical support.
• Before upgrading the smart device or its operating system, check dexcom.com/compatibility. Always update manually and verify correct device settings afterward.
• Let the date and time on the smart device automatically update when traveling across time zones or switch between standard and daylight saving times. Don’t manually change the smart

device time because the user may not get readings or alerts and it may make the time on the trend screen wrong.
• Not using supplied USB charger and cable may cause the receiver battery to not charge. Don't use if the supplied USB charger or cable is damaged.

D Special Instrument Requirements:

None.

IV Device/System Characteristics:

A Device Description:

The Dexcom G7 15 Day Continuous Glucose Monitoring System (G7 15 Day System) is an integrated continuous glucose monitoring (iCGM) system intended to continuously measure the glucose in the interstitial fluid, calculate the glucose reading and make this available to the user. The G7 15 Day System is intended for single patient use at home and requires a prescription.

The G7 15 Day System consists of the following primary components: a wearable, consisting of a sensor and transmitter worn on the body and a display device, which can be a G7 Mobile Application (Mobile App) on an iOS or Android smart device or a G7 Receiver (Receiver).

To achieve the intended functions and performance of the G7 15 Day System, one sensor and at least one display device (App or Receiver) must be used together. The user must pair the display device(s) with each unique sensor to enable communication and start a sensor session. During an active session, the sensor reports new glucose data to the display device every 5-minutes. The display device then displays glucose data and provides alerts and information signals to the user. The reportable glucose range for the G7 15 Day System is 40 mg/dL to 400 mg/dL. Glucose values below this range are reported as 'LOW' and glucose values above this range are reported as 'HIGH'. The sensor has an expected wear period of up to 15 days with an extended 12-hour grace period. The grace period allows additional time for the user to change the sensor at a convenient time.

The G7 15 Day System is an interoperable connected device that can communicate glucose readings and other information wirelessly to and from compatible electronic interfaces via the following secure wireless connections:

- Wireless communication from the transmitter directly to an interoperable device communicating through the same protocol
- The Mobile App communicates to another app on a single mobile platform
- The Mobile App communicates through the cloud to another software device
    - Dexcom Partner Web APIs: The Dexcom Partner Web APIs enable communication of CGM data to authorized client software intended to receive the data through the cloud. The Partner Web APIs is not intended to be used by automated insulin delivery systems (AID).

B Principle of Operation:

The Dexcom G7 Continuous Glucose Monitoring System detects glucose levels from the fluid just beneath the skin (interstitial fluid). The sensor probe continuously measures glucose concentration in the interstitial fluid via an enzymatic electrochemical reaction using glucose oxidase. The enzyme, glucose oxidase, catalyzes the oxidation of glucose and produces hydrogen peroxide. The production of hydrogen peroxide generates an electrical current that is proportionate to the interstitial glucose concentration. The transmitter converts the signal using an algorithm to a glucose value read in mg/dL, which is then transmitted to the receiver/mobile application for the user to see and use accordingly.

C Instrument Description Information:

1. Instrument Name:

   Dexcom G7 15 Day Continuous Glucose Monitoring System

2. Specimen Identification:

   Not applicable

3. Specimen Sampling and Handling:

   Not applicable

4. Calibration:

   The G7 Continuous Glucose Monitoring System is factory calibrated. User may enter optional calibration using fingerstick blood glucose values.

5. Quality Control:

   Not applicable

V Substantial Equivalence Information:

A Predicate Device Name(s):

Dexcom G7 Continuous Glucose Monitoring System

B Predicate 510(k) Number(s):

K240902

C Comparison with Predicate(s):

Device & Predicate Device(s):	K243214	K240902
Device Trade Name	Dexcom G7 15 Day CGM System	Dexcom G7 CGM System
General Device Characteristic Similarities		
Intended Use/Indications For Use	An integrated continuous glucose monitoring system (iCGM) is intended to automatically measure glucose in bodily fluids continuously or frequently for a specified period of time. iCGM systems are designed to reliably and securely transmit glucose measurement data to digitally connected devices, including automated insulin dosing systems, and are intended to be used alone or in conjunction with these digitally connected medical devices for the purpose of managing a disease or condition related to glycemic control.	Same
Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction.	Same
Compatibility with connected devices	Compatible with digitally connected devices, including	Same

	automated insulin dosing (AID) systems	
Measurement Range	40 - 400 mg/dL	Same
General Device Characteristic Differences		
Intended Use Population	Persons with diabetes 18 years and older	Persons with diabetes ages 2 and older
Sensor Useful Life	Up to 15 days with a 12 hour grace period	Up to 10 days with a 12 hour grace period
Sensor Warmup Period	60 minutes	27 minutes

VI Standards/Guidance Documents Referenced:

1. ISO 14971:2007, Medical devices - Application of Risk Management to Medical Devices
2. ANSI 62304:2006/A1:2016, Medical Device Software – Software Life Cycle Processes
3. IEC 62366-1:2015, Medical Devices – Application of Usability Engineering to Medical Devices
4. ANSI HE75:2009/(R) 2018, Human Factors Engineering – Design of Medical Devices
5. Design considerations for Devices intended for Home Use, Guidance to FDA Staff and Industry, November 24, 2014
6. Applying Human Factors and Usability Engineering to Medical Devices, Guidance to FDA Staff and Industry, February 3, 2016
7. Guidance for the Content of Premarket Submissions for Device Software Functions, June 14, 2023
8. Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, September 27, 2023)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

iCGM performance was evaluated in clinical studies described below in section C(3). A subset of subjects wore two iCGM Systems at the same time (N=18). Precision was evaluated by comparing the glucose reading from the two Systems worn by the same subject on the backs of both upper arms.

Coefficient of Variation (%)	Paired Absolute Difference (mg/dL)	Paired Absolute Relative Difference (%)	Number of Paired Readings	Number of Subjects
6.3	13.6	9.0	62,889	18

2. Linearity:

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

3. Analytical Specificity/Interference:

   Previously established in K213919.

   Users of the CGM System can take a standard or maximum dose of acetaminophen (up to 1 gram every 6 hours) and still use the System readings. Sensor glucose readings will be falsely higher if the user is taking more than a standard acetaminophen dose. Sensor glucose readings will also be falsely higher if the user is taking hydroxyurea. Clinicians should consider alternative glucose monitoring approaches for users taking hydroxyurea.

4. Assay Reportable Range:

   See Linearity section above.

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

   The Dexcom G7 sensor and transmitter have a storage shelf-life of up to 18 months. Shelf life was evaluated at 86°F. Sensors should be stored at 36°- 86°F and 10-90% relative humidity.

6. Detection Limit:

   If a glucose measurement is less than 40 mg/dL, the result is displayed by the system as LOW. If a glucose measurement exceeds 400 mg/dL, result is displayed as HIGH.

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 analyzer (Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer) and referred to as the “comparator method” in Section C(3) below.

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):

In the pivotal study for the Dexcom G7 15 Day CGM System in subjects ages 18 years and older, the subject device 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. 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 (N=130)

iCGM Glucose Range (mg/dL)	No. Pairs	Percent within 15 mg/dL (95% B	Percent within 40 mg/dL (95% LB)	Percent within 15% (95% LB)	Percent within 40% (95% LB)	Mean Bias, mg/dL (95% CL)
< 70	2,192	93.2 (89.3)	99.5 (98.8)	---	---	-6.0 (-8.2, -3.7)
70 - 180	10,488	---	---	85.4 (83.0)	99.7 (99.4)	-5.0 (-7.2, -2.7)
>180	7,575	---	---	88.9 (85.4)	99.9 (99.8)	-1.1 (-3.7, 1.5)

Percent and Point Accuracy by Comparator Glucose Range (N=130)

Comparator 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	1,977	96.2 (94.1)	99.9 (99.3)	---	---	-0.7 (-2.7, 1.4)
70 - 180	10,447	---	---	86.3 (83.8)	99.8 (99.6)	-3.1 (-5.2, -1.0)
>180	7,831	---	---	87.6 (84.0)	99.8 (99.5)	-5.2 (-8.1, -2.3)

Percent of iCGM values within 20% of Comparator Glucose Values

No. Pairs	No. Subjects	Percent within 20% Overall (95% LCL)	Percent Within ±20% / ±20 mg/dL on Day 1
20,255	130	93.7 (92.0)	90.7*

* N = 59 based on timing of clinic sessions.

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 comparator were also provided.

Accuracy to Comparator within iCGM Glucose Ranges (N=130)

iCGM Glucose Level (mg/dL)	No. 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	286	79.0	87.4	99.3	---	---	---	-8.3	14.9
54-69	1,906	91.5	96.0	99.7	---	---	---	-3.6	9.1
70-180	10,488	---	---	---	85.9	93.7	99.7	-2.8	8.2
181-250	2,969	---	---	---	86.0	92.8	99.9	-7.8	8.0
>250	4,606	---	---	---	92.2	97.3	100.0	-2.3	6.6

Accuracy to Comparator within Comparator Glucose Ranges (N=130)

Comparator Glucose Level (mg/dL)	No. 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	203	92.1	94.1	99.0	---	---	---	5.0	12.5
54-69	1,774	97.0	99.0	100.0	---	---	---	0.2	8.2
70-180	10,447	---	---	---	85.8	93.5	99.8	-2.0	8.2
181-250	2,983	---	---	---	87.5	94.4	99.9	-3.9	7.8
>250	4,848	---	---	---	88.8	94.3	99.8	-8.5	7.4

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 (N=130)

iCGM (mg/dL)	Comparator (mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	351-400	>400	
<40	2.0%	55.1%	40.8%	2.0%	---	---	---	---	---	---	---	49
40-60	---	53.6%	42.4%	4.0%	---	---	---	---	---	---	---	844
61-80	---	8.0%	74.2%	17.7%	0.2%	---	---	---	---	---	---	2,893
81-120	0.0%	0.1%	7.4%	78.1%	13.9%	0.3%	0.0%	0.0%	0.0%	---	---	4,269
121-160	---	---	0.0%	11.8%	73.6%	13.6%	0.8%	0.1%	0.0%	---	---	3,394
161-200	---	---	---	0.0%	15.0%	65.2%	18.5%	1.2%	0.1%	---	---	2,268
201-250	---	---	---	---	0.1%	11.1%	64.0%	20.7%	3.8%	0.3%	---	1,981
251-300	---	---	---	---	---	---	12.9%	58.1%	25.9%	3.0%	---	2,224
301-350	---	---	---	---	---	---	---	19.7%	67.9%	12.2%	0.2%	1,896
351-400	---	---	---	---	---	---	---	---	39.5%	56.4%	4.1%	486
>400	---	---	---	---	---	---	---	---	1.2%	65.9%	32.9%	82

Concurrence Analysis by Comparator Glucose Level (N=130)

Comparator (mg/dL)	iCGM (mg/dL)											N
	<40	40-60	61-80	81-120	121-160	161-200	201-250	251-300	301-350	350-400	>400	
<40	50.0%	---	---	50.0%	---	---	---	---	---	---	---	2
40-60	3.8%	63.1%	32.3%	0.8%	---	---	---	---	---	---	---	716
61-80	0.7%	12.6%	75.5%	11.2%	0.0%	---	---	---	---	---	---	2,842
81-120	0.0%	0.8%	11.9%	77.9%	9.4%	0.0%	---	---	---	---	---	4,283
121-160	---	---	0.1%	17.2%	72.7%	9.9%	0.0%	---	---	---	---	3,437
161-200	---	---	---	0.6%	21.3%	68.0%	10.1%	---	---	---	---	2,173
201-250	---	---	---	0.1%	1.3%	20.9%	63.3%	14.4%	---	---	---	2,003
251-300	---	---	---	0.1%	0.2%	1.3%	19.4%	61.3%	17.7%	---	---	2,110
301-350	---	---	---	0.0%	0.0%	0.1%	3.6%	27.0%	60.3%	9.0%	0.0%	2,136
351-400	---	---	---	---	---	---	0.9%	10.6%	36.7%	43.3%	8.5%	633
>400	---	---	---	---	---	---	---	---	7.8%	39.2%	52.9%	51

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 (N=130)

iCGM Rate (mg/dL/min)	Comparator Rate (mg/dL/min)						N
	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2	
<-2	88 (33.0)	108 (40.4)	53 (19.9)	15 (5.6)	1 (0.4)	2 (0.7)	267
-2 to -1	89 (6.1)	651 (44.3)	649 (44.1)	73 (5.0)	9 (0.6)	0 (0.0)	1,471
-1 to 0	32 (0.4)	544 (6.2)	6,498 (73.6)	1,658 (18.8)	87 (1.0)	11 (0.1)	8,830
0 to 1	7 (0.1)	76 (1.1)	1,636 (24.4)	4,266 (63.7)	642 (9.6)	73 (1.1)	6,700
1 to 2	2 (0.1)	6 (0.3)	84 (4.9)	630 (36.7)	789 (46.0)	205 (11.9)	1,716
>2	0 (0.0)	1 (0.1)	16 (2.1)	101 (13.2)	256 (33.4)	392 (51.2)	766

Note: iCGM rate of change was calculated using the slope of consecutive CGM readings compared to consecutive comparator data

Agreement When iCGM Reads 'LOW' or 'HIGH'

The subject device 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 'LOW' whenever the sensor is scanned. When the system determines that the glucose reading is above 400 mg/dL, it will display 'HIGH' 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 'LOW' or 'HIGH' are evaluated separately. The cumulative percentages of when the comparator values were less than certain glucose values (for 'LOW') and when comparator values were more that certain glucose values (for 'HIGH') are presented in the tables below.

Distribution of Comparator for iCGM Readings Below 40 mg/dL 'LOW'

iCGM-Comparator Pairs	Comparator (mg/dL)					N
	<50	<60	<70	<80	≥80	
n	16	27	42	47	2	49
Cumulative %	33	55	86	96	4	

Distribution of Comparator for iCGM Readings Above 400 mg/dL 'High'

iCGM-Comparator Pairs		Comparator (mg/dL)				N
	>340	>320	>280	>250	≤250	
n	81	82	82	82	0	82
Cumulative %	99	100	100	100	0	

Alert Performance

The tables in this section show the accuracy of the System's Low and High Glucose Alerts. The Alert Rate tells the user how often the alert 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 Alert Performance

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

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

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

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

Low Glucose Alert Performance (N=130)

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 (%)
55	1,211	47.0	53.0	298	82.6	17.4
60	1,818	65.6	34.4	726	78.7	21.3
70	4,978	82.3	17.7	2,113	92.1	7.9
80	8,249	87.1	12.9	3,583	96.2	3.8
90	11,268	90.6	9.4	4,695	97.1	2.9

High Glucose Alert Performance

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

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

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

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

High Glucose Alert Performance (N=130)

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	34,324	97.5	2.5	12,746	97.2	2.8
140	28,658	97.0	3.0	10,838	96.6	3.4
180	20,208	97.3	2.7	8,020	96.7	3.3
200	17,200	97.3	2.7	7,025	96.1	3.9
220	14,706	96.5	3.5	6,177	95.4	4.6
240	12,492	95.4	4.6	5,387	94.3	5.7
300	5,595	86.8	13.2	2,895	81.0	19.0

Sensor Stability

Sensor stability describes the performance of the sensor over the sensor lifetime. Sensors can be worn for up to 15 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 1-3)
- Early Middle (Days 4-7),
- Late Middle (Days 9-12), and
- End (Days 13-15.5).

The mean absolute relative difference (MARD) and agreement rates with the comparator method were evaluated over 15 day life of the sensor.

Sensor Accuracy Relative to Comparator Over the Wear Duration (N=130)

Wear Period	No. Pairs	MARD (%)	Within ±15% / ±15mg/dL	Within ±20% / ±20mg/dL	Within ±40% / ±40mg/dL
Beginning	5,653	8.6	84.5	93.0	99.8
Early Middle	5,507	7.4	90.4	95.8	99.9
Late Middle	5,175	7.3	90.7	96.2	99.9
End	3,920	8.9	85.3	91.6	99.5

Sensor Life

A total of 131 sensors were evaluated to determine the percentage of sensors that lasted through the 15-day sensor life. Of the 131 Sensors, 73.9% of sensors lasted the full 15 days. Some sensors were excluded from this analysis if they were scheduled to be removed prior to Day 15. For example, on or before Day 15, 60 sensors were removed by the sponsor at the last scheduled clinic visit for the subject. 25 sensors (19.1%) had "early sensor shut-off" (ESS), which is when a sensor automatically ends a sensor session as a result of self-diagnostics. Survival rates were calculated using the Kaplan Meier method.

Sensor Survival Rate Over Wear Duration

Day of Wear*	No. of Sensors	Survival Rate (%)
1	130	99.2
2	130	99.2
3	128	97.7
4	124	94.7
5	124	94.7
6	123	93.9
7	121	93.1
8	120	92.4
9	119	91.6
10	116	90.0
11	112	87.7
12	107	83.8
13	104	81.4

14	75	79.7
15	38	73.9

* Refers to the number of sensors that survived the full wear day

The pivotal clinical data was re-analyzed to censor devices where study staff assistance or supplemental adhesives were used during sensor insertion, as well as devices that were removed at a scheduled clinic visit prior to the full 15 days. The survival rate without these sensors included was 78.4% through day 15.

A separate survival study was conducted (Study 2) in which the survival rate through day 15 was 76.0% (N=95). The survival rate was re-analyzed to censor devices where application assistance or supplemental adhesives were used, as well as devices that were removed at a scheduled clinic visit prior to the full 15 days. The survival rate without these sensors included was 80.5% through day 15.

Glucose Reading Availability

The capture rate characterizes the reliability of the communication between components of the system throughout the 15-day life span of the sensor life based on information collected in the pivotal study.

Data Availability Rate by Wear Period

Day of Wear*	No. of Sensors	Capture Rate (%)
1	130	99.2
2	130	99.8
3	130	99.6
4	128	99.6
5	124	99.7
6	124	99.6
7	123	99.7
8	121	99.6
9	120	99.5
10	119	99.2
11	116	98.8
12	112	98.6
13	107	99.0
14	104	98.0
15	75	96.9

* Refers to the number of sensors that provided glucose data during the wear day

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 reference device (K234070) and are applicable to the G7 15 Day Continuous Glucose Monitoring System in this 510(k):

- Mechanical Functional Testing
- Electrical Functional Testing (except for the battery life performance)
- Wireless Performance Testing
- Medical Electrical System Safety Testing (except for the standard compliance to IEC 62304)
- Medical Electrical System Electromagnetic Compatibility & Radio Approval Testing
- Biocompatibility
- Sterilization Validation
- Packaging Validation
- Substance Restrictions and Product Waste Regulations

The following performance characteristics were verified or validated through studies conducted on the subject device, G7 15 Day CGM System:

Shelf-Life:
Shelf-Life testing was performed to evaluate the stability of the G7 15 Day CGM System under real time anticipated storage conditions and supported its useful life to be up to 18 months. The test results for the G7 15 Day Continuous Glucose Monitoring System met specifications.

Human Factors:
Human factors and usability testing of the G7 15 Day CGM System was conducted to determine whether the changes, as compared to the predicate device, impact the usability of the device. Human Factors testing was conducted in accordance with the following FDA guidance documents and recognized consensus standards:

- Design considerations for Devices intended for Home Use, Guidance to FDA Staff and Industry, November 24, 2014
- Applying Human Factors and Usability Engineering to Medical Devices, Guidance to FDA Staff and Industry, February 3, 2016
- IEC 62366-1:2015/AMD 1:2020: Medical devices – Part 1: Application of Usability Engineering to Medical Devices

- ANSI/AAMI HE75:2009/(R) 2018 – Human Factors Engineer, Design of Medical Devices

The critical, essential and frequently performed tasks were evaluated to demonstrate safe and effective use of the G7 15 Day CGM System and were identified through a use-related risk analysis (URRA), which identified critical tasks solely based on the Severity of harm and included tasks resulting from known-use problems and hazards analysis. An analysis of hazards and risks was conducted on the G7 15 Day CGM System to determine safety risks associated with use of the system. Results of the human factors study support that the intended users can use the G7 15 Day CGM System safely and effectively.

Software Verification and Validation:
Software verification and validation testing was conducted to confirm that the software used in the G7 15 Day CGM System performed in accordance with established specifications, IEC 62304 and FDA Guidance document "Guidance for the Content of Premarket Submissions for Device Software Functions," June 14, 2023. Evaluation activities included code review, unit, software verification, system integration, and system level testing which verified functionality of the device against established software requirements.

Cybersecurity:
Dexcom provided cybersecurity risk management documentation for the G7 15 Day CGM System that includes analysis of confidentiality, integrity, and availability for data, information and software related to the G7 15 Day System in accordance with the FDA Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" (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. In addition, Dexcom 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.

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.