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

I Background Information:

A 510(k) Number

K213919

B Applicant

Dexcom, Inc.

C Proprietary and Established Names

Dexcom G7 Continuous Glucose Monitoring (CGM) 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:

New device

B Measurand:

Glucose in Interstitial Fluid

C Type of Test:

Quantitative, amperometric assay (Glucose Oxidase)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Dexcom G7 Continuous Glucose Monitoring (CGM) System is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons 2 years and older.

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

The Dexcom G7 CGM System is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. The Dexcom G7 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 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 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 System for diabetes treatment decisions if they are taking hydroxyurea.
- Don't wear any Dexcom G7 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 CGM System doesn't show both a number and trend arrow as well as during the 30-minute sensor warmup period.
- Don't use if on dialysis or critically ill: The Dexcom G7 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.

- Insert only in the arm or buttocks: Don’t wear it on other sites as it may not work as expected.
- Store sensors at room temperature or in the refrigerator, between 36° F and 86° F, but not in the freezer.
- Check settings: Make sure the smart device volume is turned up, not muted, and the speaker works. When a headphone is connected, alerts will only sound through the headphone, not on the smart device speaker.
- Make sure Bluetooth is on. Otherwise, the user won't get readings or alerts.
    - Make sure the smart device settings follow Dexcom’s recommended settings. Certain phone settings such as Android's Digital Wellbeing and Apple’s Screen Time may prevent notifications if enabled.
    - Allow Dexcom G7 CGM System app notifications to show on Lock screen. This will ensure the user can receive Dexcom notifications and allow the user to see notifications without unlocking the phone.
    - Android users must allow Location Permission, Do Not Disturb Access, and Notifications to use the app.
    - Apple users must allow Critical Alerts to use the app.
- Battery: Keep the battery charged.
- Quiet Mode (Vibrate): When this setting is enabled all System alerts will vibrate. The Urgent Low Glucose and technical alerts will still escalate to sound if not acknowledged.
- Quiet Mode (Silence All): When this setting is enabled, all System alerts will be silent. The user won't receive sound or vibration for any alerts. The user will still receive visual alerts on the display device. (Exceptions: App Stopped alerts will still sound.) Check the display device frequently to avoid missing a low/high event.
- 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.

Use electrical equipment as directed:

Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches to any part of the Dexcom G7 CGM System including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Use of this equipment adjacent to, or stacked with, other equipment should be avoided because it could result in improper operation.

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. Store supplied USB charger and cable safely. Misuse of the USB cable can be a strangulation risk.

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

The Dexcom G7 Continuous Glucose Monitoring System (G7 System) is an interoperable continuous glucose monitoring (CGM) system intended to continuously measure the glucose in the interstitial fluid, calculate the glucose reading and make this value available to the user. It consists of the following components:

- G7 Glucose Sensing Subsystem (GSS)
- G7 Mobile Applications Subsystem (MAS)
- G7 Receiver Subsystem (RVS)

To achieve the intended functions and performance of the G7 System, one GSS and one receiving device (MAS or RVS) must be used together. The receiving device acts as the primary display device and the user may choose to use only the MAS or only the RVS as the sole display device; they may also choose to use both display devices simultaneously (MAS and RVS). The user must pair the receiving device(s) with each unique GSS to enable communication and start a sensor session. During an active session, the GSS reports new glucose data to a receiving device every 5-minutes. The receiving device then displays glucose data and provides alerts and information signals to the user. The reportable glucose range for the G7 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 10 days with an extended 12-hour grace period after the sensor session. The grace period allows additional time for the user to change the sensor at a convenient time.

The Dexcom G7 System is an interoperable connected device that can communicate glucose readings and other information wirelessly and securely to and from interoperable electronic interfaces; including compatible AID systems.

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 Continuous Glucose Monitoring (CGM) System

2. Specimen Identification:
   Not applicable.

3. Specimen Sampling and Handling:
   Not applicable.

4. Calibration:
   The G7 Continuous Glucose Monitoring System is factory calibrated and does not require a sensor code. 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 G6 Continuous Glucose Monitoring (CGM) System

B Predicate 510(k) Number(s):
K201328

C Comparison with Predicate(s):

Device & Predicate Device(s):	K213919	K201328
Device Trade Name	Dexcom G7 Continuous Glucose Monitoring System	Dexcom G6 Continuous Glucose Monitoring 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	Same

Device & Predicate Device(s):	K213919	K201328
	in conjunction with these digitally connected medical devices for the purpose of managing a disease or condition related to glycemic control.	
Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction.	Same
Sensor Calibration	Factory calibrated, optional manual calibration	Same
Primary Display Device	Mobile app installed on compatible smart device or Receiver	Same
Compatibility with connected devices	Compatible with digitally connected devices, including automated insulin dosing (AID) systems	Same
General Device Characteristic Differences		
Sensor Probe Dimensions	90º insertion angle	45° insertion angle
Anatomical Wear Location	Arm (age 2+ years) or upper buttocks (age 2-6 years)	Abdomen (age 2+ years) or upper buttocks (age 2-17 years)
Sensor Warm Up Time	Within 30 minutes	2 hours
Sensor Useful Life	Up to 10 days with 12 hour grace period (automatic sensor shut off)	Up to 10 days (automatic sensor shut off)
Transmitter Useful Life	Single Use (10.5 days)	Reusable (90 days)

VI Standards/Guidance Documents Referenced:

1. ISO 14971:2007, Medical devices - Application of Risk Management to Medical Devices

2. IEC 60601-1-2:2014, Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

3. IEC 60601-1-11:2015, Medical Electrical Equipment – Part 1-11 – General requirements for basic safety and essential performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems used in the Home Healthcare Environment

4. ISO 14155: 2011, Clinical investigation of medical devices for human subjects – Good clinical practice

5. IEC 62366-1:2015, Medical Devices – Application of Usability Engineering to Medical Devices

6. ISO 10993-1:2018, Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a Risk Management Process

7. ISO 10993-2:2006, Biological Evaluation of medical devices – Part 2: Animal Welfare Requirements

8. ISO 10993-3: 2014 Biological Evaluation of Medical Devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

9. ISO 10993 -5:2009, Biological Evaluation of Medical Devices - Part 5: Tests for in vitro toxicity.

10. ISO 10993-6 :2016, Biological evaluation of Medical Devices - Part 6: Tests for local effects after implantation

11. ISO 10993-7:2008, Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals

12. ISO 10993-10:2010, Biological Evaluation of Medical Devices – Part 10: Tests for irritation and delayed-type hyper sensitivity

13. ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

14. ISO 10993-12:2012, Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials

15. ISO 10993-17:2002, Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances

16. ISO 10993-18:2020, Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process

17. ISO 11607-1:2019, Packaging for terminally sterilized medical devices Part 1: Requirements for Material, Sterile Barrier Systems, and Packaging Systems

18. ISO 11607-2:2019, Packaging for terminally sterilized Medical Devices – Part 2: Validation Requirements for forming, sealing and assembly processes

19. ISO 11737 -1:2018 , Sterilization of Medical Devices - Microbiological Methods, Part 1 - Determination of a population of microorganisms on products

20. ISO 11737-2:2018, Sterilization of Medical Devices - Microbiological Methods, Part 2 Tests of sterility performed in the definition, validation and maintenance of a sterilization process

21. ISO 15223-1:2016, Medical devices – Symbol to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements

22. ISO 14644-1:2015, Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration

23. ISO 14644-2:2015, Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration

24. ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems

25. ASTM F2503-20, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

26. ISO 23908:2011, Sharps injury protection -- Requirements and test methods -- Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

27. IEC 62133-2:2017, Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes - Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From Them, For Use In Portable Applications - Part 2: Lithium Systems

28. IEC/TR 60601-4-2: 2016, Medical Electrical Equipment - PART 4-2: Guidance and Interpretation - Electromagnetic Immunity: Performance of Medical Electrical Equipment and Medical Electrical Systems

29. AIM 7351731: 2017-02-23, AIM Standard - Medical Electrical Equipment & System Electromagnetic Immunity Test for RFID Readers

30. IEEE/ANSI C63.27-2017, American National Standard for Evaluation of Wireless Coexistence

31. IEC 60417: 2002, Graphical symbols for use on equipment

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 G7 CGMs at the same time (n=82). Precision was evaluated by

comparing the glucose readings from the two systems worn on the same subject on the same location.

Precision by Insertion Site and Age

	18+ YO	7-17 YO	2-6 YO	
	Arm	**Arm**	**Arm**	**Upper Buttocks***
CGM-CGM Matched Pairs (n)	50,542	22,345	2,611	4,245
Number of Subjects (N)	43	21	9	9
Paired Absolute Difference (mg/dL)	13.8	14.4	12.8	15.4
Paired Absolute Relative Difference (%)	8.9	9.3	6.1	9.7
Coefficient of Variation (%)	6.3	6.6	4.3	6.8

*Only pediatrics aged between 2-6 YO wore devices on the upper buttocks.

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:

   Users of the Dexcom G7 Continuous Glucose Monitoring System can take a standard or maximum dose of acetaminophen (up to 1 gram every 6 hours in adults) and still use the Dexcom G7 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 System for diabetes treatment decisions if they are taking hydroxyurea.

4. Assay Reportable Range:

   See Linearity section above.

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

   The Dexcom GSS (sensor and transmitter) has a storage shelf-life of up to 9 months with the insert molded needle hub design and up to 6 months with the bonded needle hub design. Shelf life was evaluated at 35.6°-86°F and 10-90% relative humidity. 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):

   Two prospective clinical studies were conducted to evaluate the Dexcom G7 Continuous Glucose Monitoring System (Dexcom G7 CGM System or G7):

   - Study 1 – a pivotal study conducted at 12 clinic sites in the United States to evaluate the safety and effectiveness of the Dexcom G7 CGM System. A total of 482 adult and pediatric subjects (ages 2 and older) were enrolled.

- Study 2 – a pivotal study conducted at two clinic sites in the United States to evaluate the data transmission reliability of the Dexcom G7 CGM System. A total of 60 adult and pediatric subjects (ages 12 and older) were enrolled.

The G7 wearables (sensor, data-logging transmitter, and adhesive patch) worn in Study 1 logged the glucose data but did not transmit real-time glucose data to a display device. As such, Study 2 was conducted to characterize the reliability of the real-time communication between the G7 wearable and the G7 display devices.

Data from Study 1 are presented in the tables below.

iCGM Reading Accuracy to Comparator

Percent and Point Accuracy Between iCGM and Comparator by iCGM Glucose Range - ≥ 18 YO Arm (N=308)

iCGM Glucose Range (mg/dL)	Matched Pairs (N)	Percent Within 15 mg/dL (95% LB)	Percent Within 40 mg/dL (95% LB)	Percent Within 15% (95% LB)	Percent Within 40% (95% LB)	Mean Bias (mg/dL) (95% UB)
<70	4,869	92.0 (90.0)	99.5 (99.1)	----	----	-6.5 (-5.4)
70-180	18,379	----	---	85.4 (83.8)	99.5 (99.3)	-3.1 (-2.0)
>180	15,945	----	---	92.2 (91.1)	99.9 (99.9)	1.6 (2.8)

Percent and Point Accuracy Between iCGM and Comparator by iCGM Glucose Range - Pediatrics 7-17 YO Arm (N=122)

iCGM Glucose Range (mg/dL)	Matched Pairs (N)	Percent Within 15 mg/dL (95% LB)	Percent Within 40 mg/dL (95% LB)	Percent Within 15% (95% LB)	Percent Within 40 % (95% LB)	Mean Bias (mg/dL) (95% UB)
<70	881	85.7 (79.9)	96.8 (92.0)	----	----	-7.8 (-5.6)
70-180	3,996	----	----	86.0 (82.1)	99.6 (99.3)	-3.6 (-1.5)
>180	3,191	----	----	92.2 (89.4)	100.0 (99.8)	1.6 (3.9)

Percent and Point Accuracy Between iCGM and Comparator by Comparator Glucose Range - ≥ 18 YO Arm (N=308)

Comparator Glucose Range (mg/dL)	Matched Pairs (N)	Percent Within 15 mg/dL (95% LB)	Percent Within 40 mg/dL (95% LB)	Percent Within 15% (95% LB)	Percent Within 40% (95% LB)	Mean Bias (mg/dL) (95% UB)
<70	5,262	93.4 (91.8)	99.8 (99.2)	----	----	1.2 (2.2)
70-180	17,910	----	---	85.7 (84.2)	99.5 (99.3)	-0.5 (0.5)
>180	16,021	----	---	91.9 (90.6)	99.8 (99.7)	-3.9 (-2.5)

Percent and Point Accuracy Between iCGM and Comparator by Comparator Glucose Range - Pediatrics 7-17 YO Arm (N=122)

Comparator Glucose Range (mg/dL)	Matched Pairs (N)	Percent Within 15 mg/dL (95% LB)	Percent Within 40 mg/dL (95% LB)	Percent Within 15% (95% LB)	Percent Within 40% (95% LB)	Mean Bias (mg/dL) (95% UB)
<70	877	93.2 (90.2)	100.0 (100.0)	----	----	-0.2 (1.9)
70-180	3,936	----	----	87.2 (83.6)	98.6 (97.4)	-1.2 (0.7)
>180	3,255	----	----	89.8 (86.5)	99.9 (99.7)	-2.7 (-0.4)

The G7 percent and point accuracy between iCGM and the comparator is equal to or better than that of the predicate G6 CGM System (K201328).

Percent of values within 20% of comparator method were calculated across the measuring range overall, and for pediatric and adult populations.

Percent of iCGM Within 20% of Comparator Glucose by Study Population and Wear Location (N=453)

Patient Population/ Wear location	Matched Pairs (n)	Percent within 20% (95% LB)
Overall (40-400 mg/dL)		
Arm	47,261	93.5 (92.7)
18 years and up		
Arm	39,193	94.1 (93.3)
Pediatrics (7-17 years old)		
Arm	8,068	94.4 (92.7)
Pediatrics (2 - 6 years old)		
Arm	148	96.4 (90.8)
Upper buttocks	143	87.4 (79.1)

Percent of 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 for arm insertion site in adult and pediatric subjects.

System Accuracy to Comparator Within iCGM Glucose Ranges - ≥ 18 YO Arm (N=308)

iCGM Glucose Range (mg/dL)	Matched Pairs (N)	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	1,140	79.7	88.9	98.9	----	----	----	-9.3	16.0
54-69	3,729	92.8	96.1	99.3	----	----	----	-2.3	9.1
70-180	18,379	----	----	----	83.6	91.9	99.0	0.4	8.9
181-250	6,055	----	----	----	89.3	95.2	99.8	-2.7	7.5
>250	9,890	----	----	----	94.5	98.2	100.0	-2.3	6.0

System Accuracy to Comparator Within iCGM Glucose Ranges - Pediatrics 7-17 YO Arm (N=122)

iCGM Glucose Range (mg/dL)	Matched Pairs (N)	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	162	52.5	71.0	92.0	----	----	----	-17.7	24.1
54-69	719	89.8	94.0	97.4	----	----	----	-4.7	9.0
70-180	3,996	----	----	----	85.1	92.6	99.6	-0.7	8.3
181-250	1,316	----	----	----	87.9	95.9	99.9	-3.2	7.5
>250	1,875	----	----	----	94.1	99.3	100.0	-3.2	6.3

System Accuracy to Comparator Within Comparator Glucose Ranges - ≥ 18 YO Arm (N=308)

Comparator Glucose Range (mg/dL)	Matched Pairs (N)	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	732	91.0	93.7	98.8	----	----	----	4.0	14.0
54-69	4,530	92.0	97.0	99.8	----	----	----	1.1	10.7
70-180	17,910	----	----	----	84.6	92.6	99.3	1.1	8.6
181-250	5,905	----	----	----	89.9	95.0	99.6	-1.9	7.4
>250	10,116	----	----	----	92.8	97.1	99.9	-6.6	6.4

System Accuracy to Comparator Within Comparator Glucose Ranges - Pediatrics 7-17 YO Arm (N=122)

Comparator Glucose Range (mg/dL)	Matched Pairs (N)	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	66	92.4	98.5	100.0	----	----	----	2.0	10.4
54-69	811	91.0	96.9	100.0	----	----	----	0.7	9.8
70-180	3,936	----	----	----	85.5	92.4	98.6	-0.4	8.5
181-250	1,275	----	----	----	88.0	94.7	99.8	-2.3	7.6
>250	1,980	----	----	----	90.9	97.8	99.9	-7.9	6.8

Concurrence

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, 301-350, 351-400, and >400 mg/dL were evaluated against comparator glucose ranges and percent of iCGM values within those ranges were reported in the following tables.

Concurrence of iCGM and Comparator by iCGM Glucose Range - ≥ 18 YO Arm (N=308)

	Comparator Glucose Values (mg/dL)											
iCGM (mg/dL) (%)	**<40**	**40-60**	**61-80**	**81-120**	**121-160**	**161-200**	**201-250**	**251-300**	**301-350**	**351-400**	**>400**	**Total**
<40	16 7.1%	105 46.9%	97 43.3%	3 1.3%	3 1.3%							224
40-60	9 0.4%	1,418 58.0%	944 38.6%	71 2.9%	2 0.1%							2,444
61-80	1 0.0%	657 12.0%	4,134 75.4%	678 12.4%	11 0.2%	4 0.1%						5,485
81-120		49 0.7%	1,175 15.7%	5,570 74.2%	671 8.9%	30 0.4%	7 0.1%					7,502
121-160		2 0.0%	2 0.0%	855 15.5%	3,950 71.7%	636 11.5%	58 1.1%	5 0.1%				5,508
161-200			6 0.1%	9 0.2%	691 15.9%	2,916 67.0%	668 15.4%	55 1.3%	4 0.1%			4,349
201-250					9 0.2%	608 15.1%	2,687 66.9%	651 16.2%	51 1.3%	6 0.1%	3 0.1%	4,015
251-300						4 0.1%	538 12.2%	2,604 59.0%	1,187 26.9%	77 1.7%		4,410
301-350							7 0.2%	547 13.8%	2,795 70.7%	598 15.1%	6 0.2%	3,953
351-400								9 0.6%	530 34.7%	940 61.6%	48 3.1%	1,527
>400									14 5.0%	143 51.4%	121 43.5%	278

Concurrence of iCGM and Comparator by iCGM Glucose Range - Pediatrics 7-17 YO Arm (N=122)

	Comparator Glucose Values (mg/dL)											
iCGM (mg/dL) (%)	**<40**	**40-60**	**61-80**	**81-120**	**121-160**	**161-200**	**201-250**	**251-300**	**301-350**	**351-400**	**>400**	Total
<40	3 4.1%	33 44.6%	33 44.6%	5 6.8%								74
40-60		186 46.3%	196 48.8%	15 3.7%	5 1.2%							402
61-80		61 5.6%	895 82.2%	120 11.0%	11 1.0%	2 0.2%						1,089
81-120		2 0.1%	278 17.9%	1,103 70.9%	168 10.8%	5 0.3%						1,556
121-160				156 12.0%	908 70.1%	215 16.6%	16 1.2%					1,295
161-200				1 0.1%	173 18.5%	605 64.6%	148 15.8%	10 1.1%				937
201-250						122 13.3%	610 66.7%	169 18.5%	13 1.4%			914
251-300							87 12.2%	344 48.2%	279 39.1%	3 0.4%		713
301-350								86 10.9%	589 74.9%	110 14.0%	1 0.1%	786
351-400								1 0.3%	114 30.3%	240 63.8%	21 5.6%	376
>400									3 3.8%	43 55.1%	32 41.0%	78

Concurrence of iCGM and Comparator by Comparator Glucose Range - ≥ 18 YO Arm (N=308)

	Comparator Glucose Values (mg/dL)										
iCGM (mg/dL) (%)	**<40**	**40-60**	**61-80**	**81-120**	**121-160**	**161-200**	**201-250**	**251-300**	**301-350**	**351-400**	**>400**
<40	16 61.5%	105 4.7%	97 1.5%	3 0.0%	3 0.1%						
40-60	9 34.6%	1,418 63.6%	944 14.8%	71 1.0%	2 0.0%						
61-80	1 3.8%	657 29.4%	4,134 65.0%	678 9.4%	11 0.2%	4 0.1%					
81-120		49 2.2%	1,175 18.5%	5,570 77.5%	671 12.6%	30 0.7%	7 0.2%				
121-160		2 0.1%	2 0.0%	855 11.9%	3,950 74.0%	636 15.2%	58 1.5%	5 0.1%			
161-200			6 0.1%	9 0.1%	691 12.9%	2,916 69.5%	668 16.8%	55 1.4%	4 0.1%		
201-250					9 0.2%	608 14.5%	2,687 67.8%	651 16.8%	51 1.1%	6 0.3%	3 1.7%
251-300						4 0.1%	538 13.6%	2,604 67.3%	1,187 25.9%	77 4.4%	
301-350							7 0.2%	547 14.1%	2,795 61.0%	598 33.9%	6 3.4%
351-400								9 0.2%	530 11.6%	940 53.3%	48 27.0%
>400									14 0.3%	143 8.1%	121 68.0%
Total	26	2,231	6,358	7,186	5,337	4,198	3,965	3,871	4,581	1,764	178

Concurrence of iCGM and Comparator by Comparator Glucose Range - Pediatrics 7-17 YO Arm (N=122)

	Comparator Glucose Values (mg/dL)										
iCGM (mg/dL) (%)	**<40**	**40-60**	**61-80**	**81-120**	**121-160**	**161-200**	**201-250**	**251-300**	**301-350**	**351-400**	**>400**
<40	3 100.0%	33 11.7%	33 2.4%	5 0.4%							
40-60		186 66.0%	196 14.0%	15 1.1%	5 0.4%						
61-80		61 21.6%	895 63.8%	120 8.6%	11 0.9%	2 0.2%					
81-120		2 0.7%	278 19.8%	1,103 78.8%	168 13.3%	5 0.5%					
121-160				156 11.1%	908 71.8%	215 22.7%	16 1.9%				
161-200				1 0.1%	173 13.7%	605 63.8%	148 17.2%	10 1.6%			
201-250						122 12.9%	610 70.8%	169 27.7%	13 1.3%		
251-300							87 10.1%	344 56.4%	279 28.0%	3 0.8%	
301-350								86 14.1%	589 59.0%	110 27.8%	1 1.9%
351-400								1 0.2%	114 11.4%	240 60.6%	21 38.9%
>400									3 0.3%	43 10.9%	32 59.3%
Total	3	282	1,402	1,400	1,265	949	861	610	998	396	54

Tread Accuracy

Trend accuracy describes the accuracy of the sensor during times of rapidly changing glucose and are characterized by slopes, such as from >2 mg/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 minute) determined by the iCGM values and the corresponding comparator values for each iCGM-comparator measured pairs (typically collected once every 15 minutes).

Trend Accuracy Between iCGM and Comparator - ≥ 18 YO Arm (N=308)

	Comparator Rate Range (mg/dL/min)						
iCGM Rate Range (mg/dL/min) N (Row %)	**<-2**	**[-2,-1)**	**[-1,-0)**	**[0,1]**	**(1,2]**	**>2**	**Number of Paired iCGM-Comparator (Row N)**
<-2	221 (29.2)	235 (31.0)	213 (28.1)	69 (9.1)	17 (2.2)	3 (0.4)	758
[-2,-1)	209 (7.3)	989 (34.7)	1,314 (46.1)	281 (9.9)	48 (1.7)	10 (0.4)	2,851
[-1,0)	143 (1.0)	951 (6.8)	9,822 (70.3)	2,792 (20.0)	221 (1.6)	51 (0.4)	13,980
[0,1]	63 (0.6)	230 (2.0)	3,292 (29.1)	6,370 (56.4)	1,140 (10.1)	200 (1.8)	11,295
(1,2]	4 (0.1)	43 (1.3)	262 (7.9)	1,114 (33.7)	1,401 (42.4)	469 (14.2)	3,302
>2	2 (0.1)	8 (0.4)	84 (4.1)	258 (12.7)	622 (30.6)	1,058 (52.0)	2,035

Note: RoC was calculated using comparator data with consecutive measurements greater than 5 minutes

Trend Accuracy Between iCGM and Comparator - Pediatrics 7-17 YO Arm (N=122)

	Comparator Rate Range (mg/dL/min)						
iCGM Rate Range (mg/dL/min) N (Row %)	**<-2**	**[-2,-1)**	**[-1,-0)**	**[0,1]**	**(1,2]**	**>2**	**Number of Paired iCGM-Comparator (Row N)**
<-2	63 (29.6)	78 (36.6)	50 (23.5)	19 (8.9)	3 (1.4)	0 (0.0)	213
[-2,-1)	54 (6.6)	386 (47.5)	308 (37.9)	56 (6.9)	7 (0.9)	2 (0.2)	813
[-1,0)	16 (0.6)	222 (8.3)	1,860 (69.8)	522 (19.6)	37 (1.4)	9 (0.3)	2,666
[0,1]	6 (0.3)	38 (1.7)	545 (24.5)	1,403 (63.2)	202 (9.1)	27 (1.2)	2,221
(1,2]	3 (0.4)	7 (1.0)	66 (9.0)	263 (35.7)	324 (44.0)	73 (9.9)	736
>2	0 (0.0)	4 (0.9)	21 (4.6)	49 (10.8)	138 (30.4)	242 (53.3)	454

Note: RoC was calculated using comparator data with consecutive measurements greater than 5 minutes

Agreement When iCGM Reads "LOW" or "HIGH"

G7 reports glucose readings between 40 and 400 mg/dL. When G7 determines the sensor reading is below 40 mg/dL, it displays "LOW" on the receiver or mobile app. When G7 determines the glucose level is above 400 mg/dL, it displays "HIGH" on the receiver or mobile app. 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 method) when the iCGM value is classified as LOW or HIGH is evaluated separately, and the cumulative percentages when laboratory comparator values were less than certain glucose levels (for LOW), and when laboratory comparator values were greater than certain glucose levels (for HIGH) are presented in the table below.

Distribution of Comparator for iCGM Readings LOW or HIGH - Adults and Pediatrics 7-17 YO Arm (N=430)

		Comparator (mg/dL)					
iCGM Readings	**iCGM-Comparator Pairs**	**<55**	**<60**	**<70**	**<80**	**≥80**	**Total**
LOW	n	99	145	233	286	12	298
	Cumulative Percent	33	49	78	96	4	
iCGM Readings	**iCGM-Comparator Pairs**	**>340**	**>320**	**>280**	**>250**	**≤250**	**Total**
HIGH	n	347	356	356	356	0	356
	Cumulative Percent	97	100	100	100	0	

Alert Performance

The Hypoglycemic Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the % of time the device alarmed when the blood glucose level was at or below the alert setting within 15 minutes before or after the device alarmed (as confirmed by the comparator method). The False Alert Rate is the % of time the device alarmed when the blood glucose level was above the alert setting within 15 minutes before or after the device alarmed. The Correct Detection Rate is the % of time the device alarmed when the blood glucose level was at or below the alert setting within 15 minutes before or after the hypoglycemic event. The Missed Detection Rate is the % of time the device did not alarm when the blood glucose level was at or below the alert setting within 15 minutes before and after the hypoglycemic event.

Hypoglycemic Threshold Alerts and Detections - ≥ 18 YO Arm (N=308)

Hypoglycemic Alert Setting (mg/dL)	Alerts			Detections		
	# of alerts (n)	True Alert (%)	False Alert (%)	# of events (n)	True Detection (%)	Missed Detection (%)
55	2,189	51.0	49.0	1,037	75.8	24.2
60	3,504	69.7	30.3	2,263	81.1	18.9
70	7,339	86.9	13.1	5,651	88.8	11.2
80	11,893	90.2	9.8	8,645	93.7	6.3
90	16,749	92.2	7.8	10,674	96.1	3.9

Hypoglycemic Threshold Alerts and Detections - Pediatrics 7-17 YO Arm (N=122)

Hypoglycemic Alert Setting (mg/dL)	Alerts			Detections		
	# of alerts (n)	True Alert (%)	False Alert (%)	# of events (n)	True Detection (%)	Missed Detection (%)
55	462	36.8	63.2	106	80.2	19.8
60	728	59.9	40.1	288	89.2	10.8
70	1,543	81.5	18.5	976	90.4	9.6
80	2,477	89.9	10.1	1,692	92.5	7.5
90	3,415	92.4	7.6	2,059	96.8	3.2

The Hyperglycemic Alert Rate shows how often the alert is right or wrong. The True Notification Rate is the % of time the device alarmed when the blood glucose level was at or above the alert setting within 15 minutes before or after the device alarmed. The False Notification Rate is the % of time the device alarmed when the blood glucose level was below the alert setting within 15 minutes before or after the device alarmed. The Correct Detection Rate is the % of time the device alarmed when the blood glucose level was at or above the alert setting within 15 minutes before or after the hyperglycemic event. The Missed Detection Rate is the % of time the device did not alarm when the blood glucose level was at or above the alert setting within 15 minutes before and after the hyperglycemic event.

Hyperglycemic Threshold Alerts and Detections - ≥ 18 YO Arm (N=308)

Hyperglycemic Alert Setting (mg/dL)	Alerts			Detections		
	# of alerts (n)	True Alert (%)	False Alert (%)	# of events (n)	True Detection (%)	Missed Detection (%)
120	56,899	97.0	3.0	24,147	98.5	1.5
140	48,771	96.8	3.2	21,222	98.2	1.8
180	35,465	96.4	3.6	16,454	97.8	2.2
200	29,941	96.3	3.7	14,521	97.1	2.9
220	25,145	96.2	3.8	12,799	96.5	3.5
240	20,970	95.6	4.4	11,244	95.9	4.1
300	8,884	90.1	9.9	6,630	88.7	11.3

Hyperglycemic Threshold Alerts and Detections - Pediatrics 7-17 YO Arm (N=122)

Hyperglycemic Alert Setting (mg/dL)	Alerts			Detections		
	# of alerts (n)	True Alert (%)	False Alert (%)	# of events (n)	True Detection (%)	Missed Detection (%)
120	11,557	97.6	2.4	5,192	98.6	1.4
140	9,695	97.7	2.3	4,542	97.9	2.1
180	6,600	96.3	3.7	3,374	97.2	2.8
200	5,476	95.7	4.3	2,951	97.1	2.9
220	4,384	93.7	6.3	2,532	96.0	4.0
240	3,496	94.6	5.4	2,218	96.1	3.9
300	1,649	93.5	6.5	1,467	87.7	12.3

Sensor Stability

Sensor stability describes the performance over the sensor intended lifetime (up to 10 days, including the optional 12-hour grace period). Performance was estimated by calculating the percentage of iCGM 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 laboratory comparator values at the beginning (Day 1, 2), middle (Day 4, 7), and end (Day 10, 10.5) of the System lifecycle. The mean of the absolute relative difference was evaluated over the sensor life within the measuring range.

Accuracy of iCGM vs Comparator by Wear Period - ≥ 18 YO and Pediatrics 7- 17 YO Arm (N=430)

Wear Period	Matched Pairs (n)	MARD (%)	%15/15 (%)	%20/20 (%)	%40/40 (%)
Beginning	17,658	9.9	82.2	91.0	98.9
Middle	16,551	7.1	92.2	97.1	99.9
End	13,052	7.2	91.9	96.4	99.8

Sensor Life

A total of 460 sensors worn on the arm by adult and pediatric subjects were evaluated to determine the percentage of sensors that lasted through the 10-day sensor life. Seventy-nine percent (79%) of the 460 sensors lasted through the end of the entire wear period (e.g., Day 10). Among the 460 sensors evaluated, 66 sensors (14.3%) had “early sensor shut-off” where the sensor algorithm would have detected sensors that did not function as intended and shut them off.

The survival rates summarized separately for adult and pediatric populations are provided in the tables below:

Summary of System Survival by Day - ≥ 18 YO Arm (N = 315)

Day of Wear	Number of Sensors (N=315)	Survival Rate (%)
1	310	98.4
2	303	96.8
3	300	95.9
4	291	93.6
5	286	92.0
6	282	90.7
7	273	88.5
8	267	86.5
9	259	83.9
10	152	80.5

From the 315 sensors with valid CGM readings, 256 did not fail prior to Day 10 and reached the planned device removal (n=250) or were removed early due to subject withdrawal (n=6). The remaining 59 sensors (18.7%) failed before Day 10. In total, 38 sensors had early sensor shutoff (ESS) failure and 21 had adhesive failure.

Summary of System Survival by Day - Pediatrics 2-17 YO Arm (N = 145)

Day of Wear	Number of Sensors (N=145)	Survival Rate (%)
1	141	97.2
2	140	96.6
3	138	95.2
4	137	95.2
5	135	93.8
6	132	91.7
7	128	88.9
8	122	84.8
9	115	79.9
10	102	75.0

From the 145 sensors with valid CGM readings (Table 20-35), 109 did not fail prior to Day 10 and reached the planned device removal (n=108) or were removed early due to subject withdrawal (n=1). The remaining 36 sensors (24.8%) failed early. In total, 28 sensors had early sensor shutoff (ESS) failure and 8 had adhesive failures.

Summary of System Survival by Day - Pediatrics 2-6 YO Buttocks (N = 16)

Day of Wear	Number of Sensors (N=16)	Survival Rate (%)
1	15	93.8
2	13	81.3
3	13	81.3
4	13	81.3
5	13	81.3
6	13	81.3
7	11	68.8
8	10	62.5
9	10	62.5
10	8	50.0

Data Capture Rate

The data capture rate characterizes the reliability of the communication between components of the system.

The next table describes the data availability rate as the percentage of readings expected to be calculated throughout the 10-day life span of the sensor life for adults and pediatrics (arm only).

Data Availability Rate by Wear Day - Adults and Pediatrics 2-17 YO Arm (N=460) (Study 1)

Wear Day	Number of Sensors	Data Availability Rate (%)
1	460	99.5
2	451	99.8
3	443	99.9
4	438	99.7
5	428	99.6
6	421	99.6
7	414	99.5
8	401	99.2
9	389	98.5
10	374	98.1
Overall	460	99.4

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

F Other Supportive Instrument Performance Characteristics Data:

Not applicable.

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.