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

I Background Information:

A 510(k) Number

K200876

B Applicant

Dexcom, Inc.

C Proprietary and Established Names

Dexcom G6 Continuous Glucose Monitoring (CGM) System, Dexcom G6 Glucose Program 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
QDK	Class II	21 CFR 862.1355 - Integrated Continuous Glucose Monitoring System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Modification to the glucose algorithm and the G6 CGM App for Android to address the mobile device's setting for the Do Not Disturb feature.

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:
Dexcom G6 Continuous Glucose Monitoring System:

The Dexcom G6 Continuous Glucose Monitoring System (Dexcom G6 System) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons age 2 years and older.

The Dexcom G6 System is intended to replace fingerstick blood glucose testing for diabetes treatment decisions. Interpretation of the Dexcom G6 System results should be based on the glucose trends and several sequential readings over time. The Dexcom G6 System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.

The Dexcom G6 System is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. The Dexcom G6 System can be used alone or in conjunction with these digitally connected medical devices for the purpose of managing diabetes.

Dexcom G6 Glucose Program Continuous Glucose Monitoring System:

The Dexcom G6 Glucose Program Continuous Glucose Monitoring System (Dexcom Glucose Program System) is a real time, continous glucose monitoring device indicated for the management of diabetes in persons age 2 years and older.

The Dexcom Glucose Program System is intended to replace fingerstick blood glucose testing for diabetes treatement decisions for persons with diabetes who are not at significant risk of severe hypoglycemia. Interpretation of the Dexcom Glucose Program System results should be based on the glucose trends and several sequential sensor readings over time. The Dexcom Glucose Program System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating long-term therapy adjustments.

The Dexcom Glucose Program System is also intended to autonomously communicate with digitally connected devices. The Dexcom Glucose Program System can be used alone or in conjuntion with these digitally connected devices or services for the purpose of managing diabetes.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For both the Dexcom G6 System and the Dexcom Glucose Program System:

- Remove the Dexcom G6 sensor, transmitter, and receiver before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The magnetic fields and heat could damage the components of the Dexcom G6 System, which may cause it to display inaccurate blood glucose readings or may prevent alerts.
- When wearing the device, ask for hand-wanding or full-body pat-down and visual inspection instead of going through the Advanced Imaging Technology (AIT) body scanner. Also avoid putting any part of the device through baggage x-ray machine.
- This device is not intended for pregnant women, people on dialysis, or critically ill patients.
- The device should not be used to make diabetes treatment decisions when
    - The user has not used the iCGM before or is unfamiliar with the Dexcom G6 System. (It may take days, weeks or months for a user to gain confidence in using the iCGM to make treatment decisions.)
    - The user's symptoms do not match the glucose values displayed by the device.
    - The device does not show a glucose value or a trend arrow.
    - During the first two hours of sensor warm-up period, the user should use a blood glucose meter to make treatment decisions.
- Although standard dosing of acetaminophen (1000 mg per every 6 hours) does not appear to cause significant bias, higher supra-therapeutic levels of acetaminophen have shown significant positive bias.
- Sensor glucose readings will be falsely higher if the user is taking hydroxyurea. Do not use your Dexcom CGM System for diabetes treatment decisions if you are taking hydroxyurea.
- Adult users should only use the abdomen and pediatric users should only use the buttock or abdomen. Sensor performance has not been evaluated in other insertion sites and may differ from expected iCGM performance.
- If a sensor wire breaks or detaches from the sensor, it could remain under the user's skin. The user should contact their healthcare practitioner if this occurs.
- The transmitter should not be shared to avoid transmission of bloodborne illnesses.
- When using the smart device as a receiver, the user should follow the user manual instructions to ensure that all glucose values, important alarms and alerts can be seen and heard. Do not use headphones will using the smart device as a receiver. The app must always be running in the background of the smart device to ensure the user receives glucose values, alarms and alerts.
- Before updating the smart device hardware or operating system, verify the compatibility of the updated hardware/software with the device system.

For the Dexcom Glucose Program System Only:

- The Dexcom Glucose Program System does not alert or alarm the user when the glucose is low (below the target range), high (above the target range), or rapidly changing. Users should check readings often if they need to know their glucose level.

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

DEXCOM G6 CONTINOUS GLUCOSE MONITORING SYSTEM (called the DEXCOM G6 SYSTEM hereafter)
The Dexcom G6 System in an integrated continuous glucose monitoring system (iCGM) that provides continuous glucose readings which are updated every 5 minutes providing glucose levels, trends, and alerts. The System consists of three main components: a sensor, a Bluetooth Low Energy (BLE) transmitter and a BLE enabled display device (receiver and/or mobile application). The user can view glucose data on the receiver or on the G6 CGM App (i.e., a mobile medical application) running on a compatible mobile device, or on both simultaneously.

The system provides alerts and alarms which warn the user of low or impending low and high or impending high glucose levels. The user may determine their treatment based on the glucose values provided by the system.

G6 CGM Sensor

The sensor component is a sterile device that consists of the sensor applicator, plastic base ("transmitter holder"), and sensor probe. The applicator is a single use, disposable unit that contains an introducer needle holding the sensor probe. The applicator deploys the needle and inserts the sensor under the skin. The needle is retracted back into the applicator after insertion. The sensor probe continuously measures glucose concentration in interstitial fluid and can be worn for up to 10 days.

The sensor may be worn in the abdomen for adults, and both the abdomen and buttock for children ages 2-17 years old. Sensor comes with a calibration code that the user enters into the system upon initializing a new sensor. Once the code is applied, the user does not need to calibrate the system throughout the entirety of the sensor lifetime, which is 10 days. However, the user has the option to manually calibrate the system using self-measurements from a blood glucose meter in addition to entering the calibration code. Alternatively, if the user chooses not to enter the calibration code, he or she must manually calibrate the sensor by entering two fingerstick blood glucose values during start up and every 24 hours thereafter.

G6 CGM Transmitter

The G6 CGM Transmitter is a miniature radio transmitter that incorporates data processing functionality. The transmitter contains a Bluetooth radio transceiver for communication with a compatible display device (i.e., receiver and/or smart device). The transmitter attaches to the sensor and can be re-used for multiple sensing sessions up to three months.

G6 CGM Receiver

The G6 CGM Receiver is small hand-held device that wirelessly receives glucose information from the transmitter every five minutes and includes a touchscreen display. The receiver displays the current glucose reading and glucose trends to the user. It alerts the user when glucose levels are outside of a target zone and when other important system conditions occur.

Dexcom G6 System Mobile App
The G6 CGM App for iOS and G6 CGM App for Android provides an alternative display device to the receiver for users with a compatible, BLE-enabled smart device and behaves similarly to the receiver. The G6 CGM App is compatible with certain iOS, Android and Smart Device watches. The G6 CGM App for Android now includes a mechanism to ensure that mobile device operating system settings for Do Not Disturb cannot prevent the user from receiving auditory Urgent Low Glucose Alarms; this safety risk was present in previous versions of the Dexcom G6 Android Mobile App. A link to a list of compatible devices is included in the instructions for use.

The Dexcom G6 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. The G6 CGM system is designed to communicate with interoperable devices in several ways, such as described below:

- Wireless communication from the transmitter directly to an interoperable device communicating through the same protocol.
- The app communicates to another app on a single mobile platform.
- The app communicates through the cloud to another software device.

DEXCOM G6 GLUCOSE PROGRAM CONTINUOUS GLUCOSE MONITORING SYSTEM (called the DEXCOM GLUCOSE PROGRAM SYSTEM hereafter)
The Dexcom G6 Glucose Program System is an integrated continuous glucose monitoring system (iCGM) that provides continuous glucose readings which are updated every 5 minutes providing glucose levels and trends. The System consists of three main components: a sensor, a Bluetooth Low Energy (BLE) transmitter and a BLE enabled display device (receiver and/or mobile application). A user must use the Dexcom G6 Glucose Program App (i.e., a mobile medical application) running on a compatible mobile device in order to view glucose data.

G6 Glucose Program CGM Sensor
The sensor component is a sterile device that consists of the sensor applicator, plastic base ("transmitter holder"), and sensor probe. The applicator is a single use, disposable unit that contains an introducer needle holding the sensor probe. The applicator deploys the needle and inserts the sensor under the skin. The needle is retracted back into the applicator after insertion. The sensor probe continuously measures glucose concentration in interstitial fluid and can be worn for up to 10 days.

The sensor may be worn in the abdomen for adults, and both the abdomen and buttock for children ages 2-17 years old.

G6 Glucose Program Transmitter
The transmitter component is a miniature radio transmitter that incorporates data processing functionality. The transmitter contains a Bluetooth radio transceiver for communication with a compatible display device (i.e., mobile device). The transmitter attaches to the sensor and can be re-used for multiple sensing sessions up to three months.

G6 Glucose Program Mobile App
The Dexcom G6 Glucose Program CGM App for Android is the primary display for the system. The Dexcom G6 Glucose Program CGM App is compatible with specific Android devices. A link to a list of compatible devices is included in the instructions for use.

The Dexcom G6 Glucose Program CGM System is an interoperable connected device that can communicate glucose readings and other information wirelessly and securely to and from interoperable electronic interfaces. The G6 Glucose Program CGM system is designed to communicate with interoperable devices in several ways, such as described below:

- Wireless communication from the transmitter directly to an interoperable device communicating through the same protocol.
- The app communicates to another app on a single mobile platform.
- The app communicates through the cloud to another software device.

B Principle of Operation:

The Dexcom G6 System and Dexcom Glucose Program System detect 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.

Instrument Description Information:

1. Instrument Name:
   Dexcom G6 Continuous Glucose Monitoring System
   Dexcom G6 Glucose Program Continuous Glucose Monitoring System

2. Specimen Identification:
   Not applicable.

3. Specimen Sampling and Handling:
   Not applicable.

4. Calibration:
   Though the Dexcom G6 System and the Dexcom Glucose Program System do not require user calibration. Users have the option to calibrate the device manually (e.g., in situations where users do not have to use the calibration code). Therefore, a calibration stability evaluation was completed to demonstrate that the system could be calibrated manually without impact to system performance. Subjects were instructed to calibrate their CGM

devices according to the explicit system requirements. Beginning two hours after sensor insertion, calibration prompts were provided on the receiver twice the first day and every 24 hours for the remainder of the study. To demonstrate the performance of the System over a calibration cycle, the CGM-laboratory comparator percentage agreement was evaluated in 4-hour increments after calibration. Results were similar to the results obtained using the factory calibration codes.

5. Quality Control:
   Not applicable.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Dexcom G6 Continuous Glucose Monitoring System, Dexcom G6 Glucose Program Continuous Glucose Monitoring System

B Predicate 510(k) Number(s):
K191450

C Comparison with Predicate(s):

Device & Predicate Device(s):	K200876	K191450
Device Trade Name	Dexcom G6 Continuous Glucose Monitoring System	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Dexcom G6 Continuous Glucose Monitoring System (Dexcom G6 System) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons age 2 years and older.	Same
Principle of Operations	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction	Same
Data Presentation	Estimated Glucose Value (EGV)	Same

	Glucose Trend Historical Glucose Data	
Factory Calibration	Yes	Same
Optional Calibration	Yes	Same
Features	Share application to share glucose data with followers	Same
Compatibility with Intended Environments	Android OS and Apple iOS	Same
General Device Characteristic Differences		
Alarm Restrictions when using the Mobile App	G6 Android Mobile App requires users to provide the App with "Do-Not Disturb" (DND) override privileges to ensure that user receives the Urgent Low Glucose Auditory Alarm	Does not alarm when the Android device is set at the most restrictive "Do-Not Disturb" (DND) settings
Glucose Value Estimation Algorithm	Optimized Joint Probability Algorithm	Joint Probability Algorithm
Algorithm Self-Diagnostics	Optimized Noise Management Optimized Progressive Sensor Decline detection	Noise Management Progressive Sensor Decline (PSD) detection

Device & Predicate Device(s):	K200876	K193642
Device Trade Name	Dexcom G6 Glucose Program Continuous Glucose Monitoring System	Same
General Device Characteristic Similarities		
Intended Use/Indications For Use	The Dexcom G6 Glucose Program Continuous Glucose Monitoring System (Dexcom Glucose Program System) is a real time, continuous glucose monitoring device indicated for the	Same

	management of diabetes in persons age 2 years and older.	
Principle of Operations	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction	Same
Data Presentation	Estimated Glucose Value (EGV) Glucose Trend Historical Glucose Data Time in Range	Same
Factory Calibration	Yes	Same
Optional Calibration	Yes	Same
Features	Share application to share glucose data with followers Chat with Wellness Coach	Same
Compatibility with Intended Environments	Android OS and Apple iOS	Same
General Device Characteristic Differences		
Glucose Value Estimation Algorithm	Optimized Joint Probability Algorithm	Joint Probability Algorithm
Algorithm Self-Diagnostics	Optimized Noise Management Optimized Progressive Sensor Decline detection	Noise Management Progressive Sensor Decline (PSD) detection

VI Standards/Guidance Documents Referenced:

1. ISO 10993-1:2009/AC:2010; Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
2. ISO 10993-3:2009; Biological Evaluation of Medical Devices – Part 3: Tests For Genotoxicity, Carcinogenicity and Reproductive Toxicity
3. ISO 10993-5:2009; Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity
4. ISO 10993-6:2016; Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects after Implantation

5. ISO 10993-10:2013; Biological evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
6. ISO 10993-11; 2009; Biological Evaluation of Medical Devices – Part 11: Test for Systemic Toxicity
7. ISO 11137-1:2006/A1:2013; Sterilization of Health Care Products – Radiation – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices
8. ISO 11607-1:2014; Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Material, Sterile Barrier Systems, and Packaging Systems
9. ISO 11607-2:2006/A1:2014; Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes
10. ISO 11737-1:2006/AC:2009; Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Products
11. ISO 11737-2:2009; Sterilization of Medical Devices – Microbiological Methods – Part 2: Tests of Sterility Performed in the Definition, Validation and Maintenance of a Sterilization Process
12. ISO 23908:2013; Sharps Injury Protection. Requirements and Test Methods. Sharps Protection Features for Single-Use Hypodermic Needles, Introducers for Catheters and Needles Used for Blood Sampling
13. ISO 14971:2012; Medical Devices – Application of Risk Management to Medical Devices
14. ISO 11137-3:2006; Sterilization of Health Care Products – Radiation – Part 3 – Guidance on Dosimetric Aspects
15. ISO 7010:2012; Graphical Symbols – Safety Colors and Safety Signs – Registered Safety Signs
16. ISO 15223-1:2012; Medical Devices – Symbols to be Used with Medical Device Labels, Labeling and Information to be Supplied – Part 1: General Requirements
17. EN 62304:2006/AC:2008; Medical device software – Software life cycle processes
18. EN 62304:2006/AC:2015; Medical device software – Software life cycle processes
19. BS EN 62366:2015; Medical devices – Application of usability engineering to medical devices
20. EN 60601-1:2006/A1:2013; Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
21. EN 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
22. 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 home healthcare environment
23. ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012; Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
24. ASTM F2096-11; Standard test method for detecting gross leaks in packaging by internal pressurization
25. ASTM F88/F88M-15; Standard test method for seal strength of flexible barrier materials
26. ANSI/AAMI/IEC 60601-1-8:2006 & A1:2012, IEC 60601-1:2006/A1:2013; MEDICAL ELECTRICAL EQUIPMENT – Part 1-8: General requirements for basic

safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

27. IEC 60417-DB-12M:2002; Graphical symbols for use on equipment
28. IEC 60601-1-2:2014; Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
29. IEC 60086-4:2014; Primary batteries – Part 4: Safety of lithium batteries
30. IEC 62133 Edition 2.0:2012; (Battery Cell) 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
31. 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
32. USP Chapter <151>; Pyrogen Test
33. USP Chapter <161>; Transfusion and infusion assemblies and similar medical devices – Bacterial Endotoxin and Pyrogen Tests
34. FCC: Part 15 (2016); Radio Frequency Devices, Conducted Limits, Section 15.207 and Section 15.247
35. FAA AC No. 91.21-1C; Use of Portable Electronic Devices Aboard Aircraft
36. UL 1642 Fifth Edition, Revision, March 15, 2012; Standard for Safety, Lithium Batteries

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

The optimized joint probability algorithm in the modified Dexcom G6 Continuous Glucose Monitoring System and the Dexcom G6 Glucose Program Continuous Glucose Monitoring System was developed independently from the clinical validation dataset. Because the two systems use the same modified glucose algorithm, the following sections represent the performance for both Systems. iCGM performance was previously evaluated in clinical studies described in DEN170088. The raw data was reprocessed using the updated algorithm in K200876.

1. Precision/Reproducibility:

   iCGM performance was evaluated in clinical studies described in Section C(3) below. A subset of randomly selected subjects (n=67) wore two devices concurrently (blinded and unblinded iCGM Systems) at the same sensor insertion site (two in abdomen or two in buttock) to evaluate the device precision. A table of the sensor site distribution is provided below.

   Another subset of randomly-selected pediatric subjects (n=28) wore one device in the abdomen and a second device in the buttock concurrently to evaluate agreement of device measurements between different sensor insertion sites.

Precision by Insertion Site and Age

	Adults (18+ YO) - Abdomen	**Pediatrics (6-17 YO) - Abdomen**	**Pediatrics (6-17 YO) – Upper Buttocks**	**Pediatrics (2-5 YO) – Upper Buttocks**
CGM-CGM Matched pairs (n)	23,466	1,262	12,593	2,637
Number of Subjects	34	3	25	5
Paired Absolute Difference (mg/dL)	14.2	14.4	16.7	9.2
Paired Absolute Relative Difference (%)	9.0	9.3	10.7	5.1
Coefficient of Variation (%)	8.2	7.6	8.9	4.6

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:

   Interference was previously assessed in DEN170088 and was not impacted by the algorithm modifications.

4. Assay Reportable Range:

   See Linearity section above.

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

   The sensor has a storage shelf-life of 12 months. Shelf life was evaluated at 32º-86º F and 10-90% relative humidity. Sensors should be stored at 32º-86º F.

   The Dexcom G6 CGM System and the Dexcom Glucose Program System transmitters have sufficient battery life to function for 3 months as intended following its maximum storage time of 8 months. Shelf life was evaluated at 32º-113º F and 10-95% relative humidity.

6. Detection Limit:
   If a glucose measurement is less than 40 mg/dL, the result is displayed by the system as ‘Lo’. If a glucose measurement exceeds 400 mg/dL, result is displayed as ‘Hi’. Data supporting this claimed measurement range was generated in the clinical study described in Section C(3) below.

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" in the tables 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):

   The following sections represent the performance for both the Dexcom G6 CGM System and the Dexcom G6 Glucose Program System:

   Two clinical studies were previously conducted to support the accuracy performance of the predicate device; See DEN170088 for clinical study details. The clinical study raw data was reprocessed using the updated algorithm. The pediatric study included one additional subject following the data reprocessing as a result of the algorithm modifications; the sensor used in the additional pediatric subject was not declined by the updated algorithm, whereas the previous algorithm eliminated the sensor before the end-of-life (i.e., 10 days).

The following tables present the data from the reprocessed study algorithm:

Percent and Point Accuracy by iCGM Glucose Range: Adults (N=159)

iCGM Glucose Range	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 mg/dL	1,888	89.7 (87.1)	99.5 (99.0)	----	----	-1.4 (-0.3)
70-180 mg/dL	9,433	----	----	74.1 (71.6)	99.3 (99.1)	-2.7 (-1.0)
>180 mg/dL	7,991	----	----	85.3 (82.7)	99.9 (99.9)	-7.0 (-3.9)

Percent and Point Accuracy by iCGM Glucose Range: Pediatrics (N=166)

iCGM Glucose Range	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 mg/dL	350	76.9 (68.2)	95.4 (91.6)	----	----	-8.4 (-5.2)
70-180 mg/dL	3,170	----	----	79.4 (76.1)	99.3 (98.9)	-0.7 (1.0)
>180 mg/dL	2,296	----	----	85.5 (81.4)	99.9 (99.8)	2.6 (6.3)

Percent and Point Accuracy by Comparator Glucose Range: Adults (N=159)

Comparator Glucose Range	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 mg/dL	2,252	88.9 (86.4)	99.9 (99.6)	----	----	4.5 (5.5)
70-180 mg/dL	8,675	----	----	77.2 (74.6)	99.7 (99.5)	-0.7 (0.9)
>180 mg/dL	8,385	----	----	83.1 (80.0)	99.8 (99.6)	-10.5 (-7.6)

Percent and Point Accuracy by Comparator Glucose Range: Pediatrics (N=166)

Comparator Glucose Range	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 mg/dL	356	87.6 (82.8)	100.0 (100.0)	----	----	3.1 (4.8)
70-180 mg/dL	3,108	----	----	79.8 (76.5)	98.9 (98.3)	1.8 (3.4)
>180 mg/dL	2,352	----	----	84.3 (79.8)	99.7 (99.5)	-2.5 (1.4)

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

Percent of iCGM values within 20% of Reference Blood Glucose

iCGM Glucose Range	Matched Pairs (N)	Percent within 20% (95% LB)
Overall (40-400 mg/dL)	25,128	90.0 (88.8)
Adults (18 years and up)	19,312	89.7 (88.4)
Pediatrics (6-17 years old)	5,816	91.0 (88.6)
Pediatrics (2-5 years old)*	82	90.2 (84.5)

*Subjects 2-5 years old were compared to an SMBG reference
*95% LB is the lower bound of the confidence interval

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 laboratory comparator were also provided for abdominal insertion site in adult subjects, and both buttock and abdominal insertion site in pediatric populations. For pediatric subjects ages 6 and under, values were compared to SMBG.

System Accuracy to Comparator within iCGM Glucose Ranges (Adults N=159)

iCGM Glucose Range[1] (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	374	86.6	92.0	98.7	----	----	----	-6.4	13.3
54-69	1,514	90.5	95.8	99.7	----	----	----	-0.2	11.2
70-180	9,433	----	----	----	74.1	86.8	99.3	-2.7	10.9
181-250	4,106	----	----	----	80.0	92.0	99.9	-10.0	9.3
>250	3,885	----	----	----	91.0	97.7	100.0	-3.8	7.1

System Accuracy to Comparator within iCGM Glucose Ranges (Pediatrics N=166)

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	86	51.2	66.3	90.7	----	----	----	-16.9	24.1
54-69	264	85.2	89.0	97.0	----	----	----	-5.7	13.1
70-180	3,170	----	----	----	79.4	90.5	99.3	-0.7	9.8
181-250	1,373	----	----	----	83.3	93.5	99.9	-1.6	8.9
>250	923	----	----	----	88.7	96.1	99.9	8.9	7.5

System Accuracy to Comparator within iCGM Glucose Ranges (Pediatrics, Abdomen; N=99)

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	55	43.6	58.2	89.1	----	----	----	-18.9	25.8
54-69	175	88.0	89.7	96.6	----	----	----	-5.5	12.8
70-180	1,924	----	----	----	80.1	90.7	99.2	-1.6	9.8
181-250	788	----	----	----	81.7	94.8	100.0	-2.7	9.2
>250	579	----	----	----	88.6	96.9	99.8	7.5	7.5

System Accuracy to Comparator within iCGM Glucose Ranges (Pediatrics, Buttock; N=67)

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	31	64.5	80.6	93.5	----	----	----	-13.4	21.1
54-69	89	79.8	87.6	97.8	----	----	----	-6.0	13.7
70-180	1,246	----	----	----	78.4	90.0	99.4	0.7	9.7
181-250	585	----	----	----	85.5	91.8	99.8	-0.1	8.5
>250	344	----	----	----	89.0	94.8	100.0	11.3	7.4

System Accuracy to Comparator within Comparator Glucose Ranges (Adults; N=159)

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	481	88.1	95.8	99.8	----	----	----	6.0	15.8
54-69	1,771	89.0	96.2	99.9	----	----	----	4.1	12.3
70-180	8,675	----	----	----	77.2	89.4	99.7	-0.7	10.2
181-250	3,949	----	----	----	82.9	92.9	99.8	-7.1	8.8
>250	4,436	----	----	----	83.3	93.2	99.8	-13.6	8.6

System Accuracy to Comparator within Comparator Glucose Ranges (Pediatrics; N=166)

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	47	95.7	100.0	100.0	----	----	----	4.9	11.6
54-69	309	86.4	95.8	100.0	----	----	----	2.8	13.5
70-180	3,108	----	----	----	79.8	90.6	98.9	1.8	9.8
181-250	1,424	----	----	----	84.3	92.7	99.6	-1.5	9.1
>250	928	----	----	----	84.3	93.9	99.9	-4.0	8.2

System Accuracy to Comparator within Comparator Glucose Ranges (Pediatrics, Abdomen; N=99)

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	28	100.0	100.0	100.0	----	----	----	4.0	11.0
54-69	201	90.0	96.0	100.0	----	----	----	3.0	12.8
70-180	1,898	----	----	----	79.7	90.1	98.7	0.8	9.9
181-250	782	----	----	----	83.8	93.7	99.2	-2.6	9.4
>250	612	----	----	----	84.5	95.6	99.8	-4.9	8.3

System Accuracy to Comparator within Comparator Glucose Ranges (Pediatrics, Buttocks; N=67)

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	19	89.5	100.0	100.0	----	----	----	6.2	12.6
54-69	108	79.6	95.4	100.0	----	----	----	2.5	14.8
70-180	1,210	----	----	----	80.0	91.4	99.3	3.4	9.5
181-250	642	----	----	----	85.0	91.4	100.0	-0.1	8.8
>250	316	----	----	----	83.9	90.5	100.0	-2.1	7.9

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 System Readings and Comparator Values by iCGM Glucose Ranges (Adults; N=159)

	Comparator Glucose Values (mg/dL)											
iCGM Glucose Range (mg/dL)	**<40**	**40-60**	**61-80**	**81-120**	**121-160**	**161-200**	**201-250**	**251-300**	**301-350**	**351-400**	**>400**	**Total**
< 40	14 14.0%	57 57.0%	23 23.0%	4 4.0%	2 2.0%							100
40-60	11 1.2%	619 68.6%	250 27.7%	19 2.1%	2 0.2%	1 0.1%						902
61-80	2 0.1%	479 21.3%	1,392 61.8%	374 16.6%	5 0.2%	2 0.1%						2,254
81-120		15 0.4%	510 13.6%	2,653 70.5%	561 14.9%	21 0.6%	1 0.0%					3,761
121-160			1 0.0%	428 14.1%	1,950 64.4%	607 20.1%	38 1.3%	1 0.0%	1 0.0%			3,026
161-200				3 0.1%	376 14.4%	1,478 56.7%	701 26.9%	43 1.6%	7 0.3%	1 0.0%		2,609
201-250					5 0.2%	349 12.1%	1,707 59.4%	733 25.5%	80 2.8%	1 0.0%		2,875
251-300						2 0.1%	312 13.7%	1,345 59.0%	577 25.3%	43 1.9%		2,279
301-350							2 0.2%	269 22.0%	777 63.6%	168 13.7%	6 0.5%	1,222
351-400								3 0.8%	170 44.3%	200 52.1%	11 2.9%	384
> 400									2 5.7%	27 77.1%	6 17.1%	35
Total	27	1,170	2,176	3,481	2,901	2,460	2,761	2,394	1,614	440	23	19,447

Concurrence of System Readings and Comparator Values by iCGM Glucose Ranges (Pediatrics; N=166)

	Comparator Glucose Values (mg/dL)											
iCGM Glucose Range (mg/dL)	**<40**	**40-60**	**61-80**	**81-120**	**121-160**	**161-200**	**201-250**	**251-300**	**301-350**	**351-400**	**>400**	**Total**
< 40	1 3.8%	8 30.8%	6 23.1%	10 38.5%	1 3.8%							26
40-60	1 0.6%	62 39.2%	72 45.6%	19 12.0%	4 2.5%							158
61-80		55 11.3%	320 65.7%	101 20.7%	11 2.3%							487
81-120		2 0.2%	160 12.4%	980 76.1%	137 10.6%	7 0.5%	1 0.1%					1,287
121-160				137 13.3%	733 71.2%	141 13.7%	17 1.7%	1 0.1%				1,029
161-200				2 0.2%	203 18.5%	653 59.6%	221 20.2%	17 1.6%				1,096
201-250					1 0.1%	157 18.8%	533 63.8%	133 15.9%	12 1.4%			836
251-300						1 0.2%	154 28.0%	325 59.1%	68 12.4%	2 0.4%		550
301-350							3 1.0%	94 32.6%	163 56.6%	28 9.7%		288
351-400								5 5.9%	45 52.9%	33 38.8%	2 2.4%	85
> 400									1 5.0%	11 55.0%	8 40.0%	20
Total	2	127	558	1,249	1,090	959	929	575	289	74	10	5,862

Concurrence of System Readings and Comparator Values by Comparator Glucose Ranges (Adults; N=159)

	Comparator Glucose Values (mg/dL)											
iCGM Glucose Range (mg/dL)	**<40**	**40-60**	**61-80**	**81-120**	**121-160**	**161-200**	**201-250**	**251-300**	**301-350**	**351-400**	**>400**	**Total**
< 40	14 51.9%	57 4.9%	23 1.1%	4 0.1%	2 0.1%							100
40-60	11 40.7%	619 52.9%	250 11.5%	19 0.5%	2 0.1%	1 0.0%						902
61-80	2 7.4%	479 40.9%	1,392 64.0%	374 10.7%	5 0.2%	2 0.1%						2,254
81-120		15 1.3%	510 23.4%	2,653 76.2%	561 19.3%	21 0.9%	1 0.0%					3,761
121-160			1 0.0%	428 12.3%	1,950 67.2%	607 24.7%	38 1.4%	1 0.0%	1 0.1%			3,026
161-200				3 0.1%	376 13.0%	1,478 60.1%	701 25.4%	43 1.8%	7 0.4%	1 0.2%		2,609
201-250					5 0.2%	349 14.2%	1,707 61.8%	733 30.6%	80 5.0%	1 0.2%		2,875
251-300						2 0.1%	312 11.3%	1,345 56.2%	577 35.7%	43 9.8%		2,279
301-350							2 0.1%	269 11.2%	777 48.1%	168 38.2%	6 26.1%	1,222
351-400								3 0.1%	170 10.5%	200 45.5%	11 47.8%	384
> 400									2 0.1%	27 6.1%	6 26.1%	35
Total	27	1,170	2,176	3,481	2,901	2,460	2,761	2,394	1,614	440	23	19,447

Concurrence of System Readings and Comparator Values by Comparator Glucose Ranges (Pediatrics; N=166)

	Comparator Glucose Values (mg/dL)											
iCGM Glucose Range (mg/dL)	**<40**	**40-60**	**61-80**	**81-120**	**121-160**	**161-200**	**201-250**	**251-300**	**301-350**	**351-400**	**>400**	**Total**
< 40	1 50.0%	8 6.3%	6 1.1%	10 0.8%	1 0.1%							26
40-60	1 50.0%	62 48.8%	72 12.9%	19 1.5%	4 0.4%							158
61-80		55 43.3%	320 57.3%	101 8.1%	11 1.0%							487
81-120		2 1.6%	160 28.7%	980 78.5%	137 12.6%	7 0.7%	1 0.1%					1,287
121-160				137 11.0%	733 67.2%	141 14.7%	17 1.8%	1 0.2%				1,029
161-200				2 0.2%	203 18.6%	653 68.1%	221 23.8%	17 3.0%				1,096
201-250					1 0.1%	157 16.4%	533 57.4%	133 23.1%	12 4.2%			836
251-300						1 0.1%	154 16.6%	325 56.5%	68 23.5%	2 2.7%		550
301-350							3 0.3%	94 16.3%	163 56.4%	28 37.8%		288
351-400								5 0.9%	45 15.6%	33 44.6%	2 20.0%	85
> 400									1 0.3%	11 14.9%	8 80.0%	20
Total	2	127	558	1,249	1,090	959	929	575	289	74	10	5,862

Trend 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 (Adults; n=159)

iCGM Rate Range (mg/dL/min)	Comparator Rate Range (mg/dL/min)						iCGM-Comparator Matched Pairs (n)
	<-2	[-2,-1)	[-1,-0)	[0,1]	(1,2]	>2	
<-2	250 (53.0%)	163 (34.5%)	49 (10.4%)	8 (1.7%)	1 (0.2%)	1 (0.2%)	472
[-2,-1)	153 (7.4%)	1,179 (56.8%)	677 (32.6%)	62 (3.0%)	5 (0.2%)	1 (0.0%)	2,077
[-1,0)	34 (0.4%)	763 (9.6%)	6,129 (76.8%)	1,000 (12.5%)	47 (0.6%)	9 (0.1%)	7,982
[0,1]	3 (0.1%)	48 (0.9%)	1,353 (26.1%)	3,151 (60.8%)	548 (10.6%)	81 (1.6%)	5,184
(1,2]	0 (0.0%)	10 (0.6%)	62 (3.6%)	467 (26.8%)	915 (52.5%)	289 (16.6%)	1,743
>2	1 (0.1%)	2 (0.1%)	9 (0.7%)	71 (5.2%)	298 (21.9%)	979 (72.0%)	1,360

Trend Accuracy (Pediatrics; N=166)

iCGM Rate Range (mg/dL/min)	Comparator Rate Range (mg/dL/min)						iCGM-Comparator Matched Pairs (n)
	<-2	[-2,-1)	[-1,-0)	[0,1]	(1,2]	>2	
<-2	108 (48.6%)	78 (35.1%)	29 (13.1%)	6 (2.7%)	0 (0.0%)	1 (0.5%)	222
[-2,-1)	44 (6.4%)	382 (55.4%)	234 (34.0%)	24 (3.5%)	4 (0.6%)	1 (0.1%)	689
[-1,0)	10 (0.5%)	186 (9.0%)	1,514 (73.6%)	328 (15.9%)	19 (0.9%)	1 (0.0%)	2,058
[0,1]	1 (0.1%)	14 (0.8%)	430 (25.6%)	1,053 (62.7%)	166 (9.9%)	16 (1.0%)	1,680
(1,2]	0 (0.0%)	5 (0.9%)	23 (4.2%)	193 (35.3%)	261 (47.7%)	65 (11.9%)	547
>2	1 (0.2%)	1 (0.2%)	11 (2.5%)	32 (7.4%)	103 (23.8%)	284 (65.7%)	432

Agreement When iCGM Reads "LOW" or "HIGH"

The Dexcom G6 System and the Dexcom Glucose Program System report glucose readings between 40 and 400 mg/dL. When the system determines the glucose reading is below 40 mg/dL, it displays "LOW" in the Receiver or Mobile Application Status Box. When the system determines that the glucose level is above 400 mg/dL, it displays "HIGH" in the Receiver or Mobile Application Status Box. 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 laboratory comparator analyzer) 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 Reference Values when CGM readings are “Low” or “High”

iCGM Readings (mg/dL)	**iCGM-comparator Pairs**	**Comparator (mg/dL)**					**Total**
		< 55	**< 60**	**< 70**	**< 80**	**≥ 80**	
"LOW"	n	65	78	92	109	17	126
	Cumulative Percent	52%	62%	73%	87%	13%	
iCGM Readings (mg/dL)	**iCGM-comparator Pairs**	**Comparator (mg/dL)**					**Total**
		> 340	**> 320**	**> 280**	**> 250**	**≤ 250**	
"HIGH"	n	54	54	55	55	0	55
	Cumulative Percent	98%	98%	100%	100%	0%	

Alert performance:

The Hypoglycemic 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 below the alert setting within 15 minutes before or after the device alarmed (as confirmed by the comparator method). The False Notification 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 Alert and Detection Rate Evaluations (Adults; n=159)

Alert Setting	Hypo Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)	Hypo Alerts (n)	True Notification Rate (%)	False Notification Rate (%)
55 mg/dL	639	64.2	35.8	1,362	68.9	31.1
60 mg/dL	1,149	74.2	25.8	2,313	75.9	24.1
70 mg/dL	2,348	85.9	14.1	4,986	86.3	13.7
80 mg/dL	3,346	92.7	7.3	8,078	89.5	10.5
90 mg/dL	4,255	94.5	5.5	11,022	89.6	10.4

Hypoglycemic Alert and Detection Rate Evaluations (Pediatrics; n=166)

Alert Setting	Hypo Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)	Hypo Alerts (n)	True Notification Rate (%)	False Notification Rate (%)
55 mg/dL	66	68.2	31.8	326	35.0	65.0
60 mg/dL	119	73.1	26.9	486	47.5	52.5
70 mg/dL	369	81.6	18.4	1,030	70.0	30.0
80 mg/dL	669	88.0	12.0	1,766	81.7	18.3
90 mg/dL	1,030	92.8	7.2	2,722	87.3	12.7

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 Alert and Detection Rate Evaluations (Adults; n=159)

Alert Setting	Hyper Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)	Hyper Alerts (n)	True Notification Rate (%)	False Notification Rate (%)
120 mg/dL	12,676	97.7	2.3	37,167	97.5	2.5
140 mg/dL	11,194	96.9	3.1	32,263	97.2	2.8
180 mg/dL	8,484	95.3	4.7	23,521	96.6	3.4
200 mg/dL	7,296	93.7	6.3	19,664	96.0	4.0
220 mg/dL	6,179	91.3	8.7	15,763	95.7	4.3
240 mg/dL	5,040	88.7	11.3	12,337	94.6	5.4
300 mg/dL	2,120	75.0	25.0	4,243	86.0	14.0

Hyperglycemic Alert and Detection Rate Evaluations (Pediatric; n=166)

Alert Setting	Hyper Events (n)	Correct Detection Rate (%)	Missed Detection Rate (%)	Hyper Alerts (n)	True Notification Rate (%)	False Notification Rate (%)
120 mg/dL	3,962	98.0	2.0	11,800	97.3	2.7
140 mg/dL	3,419	97.5	2.5	10,200	96.2	3.8
180 mg/dL	2,390	94.5	5.5	6,872	93.5	6.5
200 mg/dL	1,895	91.2	8.8	5,233	93.4	6.6
220 mg/dL	1,470	91.8	8.2	4,128	90.4	9.6
240 mg/dL	1,108	90.0	10.0	3,091	86.9	13.1
300 mg/dL	382	83.8	16.2	1,012	77.2	22.8

Sensor Stability:

Sensor stability describes the performance over the sensor lifetime. Sensors can be worn for up to 10 days. 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, 5), and end (Day 7, 10) of the System lifecycle. The mean of the absolute relative differences were evaluated over the 10-day life of the sensor within the measuring range.

Sensor Stability Relative to Comparator (Accuracy Over Time)

Wear Period	Matched Pairs (N)	MARD (%)	Percent within %15/15 (%)	Percent within %20/20 (%)	Percent within %40/40 (%)
Beginning	8,864	10.7	77.6	89.1	99.6
Middle	7,755	9.2	84.2	94.5	99.8
End	8,509	9.5	82.7	92.2	99.6

Sensor Life:

A total of 374 sensors were evaluated to determine the percentage of sensors that lasted through the 10 day sensor life. Eighty-four percent (84%) of the sensors lasted through the end of the entire wear period (e.g., Day 10) (see Figure 1). Among the 374 sensors evaluated, 36 sensors (9.6%) had "early sensor shut-off" where the sensor algorithm would have detected sensors that did not function as intended and shut them off.

Sensor Survival Rate by Wear Day (Adults; n=164)

Wear Day	Number of Sensors	Survival Rate (%)
1	162	99.4%
2	160	98.8%
3	158	98.8%
4	155	98.8%
5	155	98.8%
6	154	98.1%
7	150	96.8%
8	145	96.2%
9	143	94.9%
10	138	93.5%

Sensor Survival Rate by Wear Day (Pediatrics; n=210)

Wear Day	Number of Sensors	Survival Rate (%)
1	206	99.0%
2	204	99.0%
3	196	97.1%
4	193	95.6%
5	187	92.6%
6	176	89.6%
7	165	86.5%
8	158	82.8%
9	148	79.7%
10	142	75.7%

The capture rate characterizes the reliability of the communication between components of the system. The System provides a sensor glucose reading every 5 minutes, or up to 288 readings per day. The percentage of readings expected to be received from the system over the sensor life was evaluated from 374 sensors and is 98.6%. More than 97% of the sensors captured readings at least 90% of the time. The table below describes the percent of readings received throughout the life span of the sensor (capture rate).

Reading Capture Rate by Wear Day (n=374)

Wear Day	Number of Sensors	Capture Rate (%)
1	374	97.9
2	368	98.8
3	364	98.9
4	354	99.0
5	348	98.8
6	342	98.2
7	330	99.0
8	315	99.0
9	303	98.6
10	291	98.4

D Clinical Cut-Off:
Not applicable.

E Expected Values/Reference Range:
Not applicable.

F Other Supportive Instrument Performance Characteristics Data:

The following supportive instrument performance characteristics were established in the respective predicate for the Dexcom G6 System (k191450) and the Dexcom Glucose Program System (k193642), and are not affected by the modifications in glucose algorithm in the current 510(k):

- Human Factors
- Sterility
- Biocompatibility
- Mechanical Engineering
- Electromagnetic Compatibility
- Wireless
- Electrical Safety
- Environmental Testing
- Shelf-Life Stability
- Packaging Integrity/Shipping Integrity
- Interoperability
- Cybersecurity
- Contact Resistance
- G6 Android Mobile App has been updated to include “Do-Not Disturb” (DND) override privileges to ensure that users receive auditory Urgent Low Glucose Alarms which were not being generated in previous versions of the Dexcom G6 Mobile App and presented a safety risk to users who did not have the dedicated CGM Receiver.

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.