

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

**I Background Information:**

**A 510(k) Number**

K191833

**B Applicant**

Dexcom, Inc.

**C Proprietary and Established Names**

Dexcom G6 Pro Continuous Glucose Monitoring System,

**D Regulatory Information**

Product Code(s)	Classification	Regulation Section	Panel
QII	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 G6 Pro Continuous Glucose Monitoring System (Dexcom G6 Pro System) is a real time continuous glucose monitoring device indicated for the management of diabetes in persons age 2 years and older in a home environment while under the supervision of a healthcare professional. The Dexcom G6 Pro System is intended to replace fingerstick blood glucose testing for diabetes treatment decisions. Interpretation of the real-time Dexcom G6 Pro System results should be based on the glucose trends and several sequential readings over time.

The Dexcom G6 Pro System may also be used as a retrospective glucose recording device indicated for assessing glycemic variability in persons age 2 years and older in a home environment while under the supervision of a healthcare professional. Retrospective interpretation of data recorded by the Dexcom G6 Pro System should be conducted solely by a healthcare professional.

The Dexcom G6 Pro System aids in detecting glucose excursions facilitating care plan adjustments. The Dexcom G6 Pro System is also intended to interface with digitally connected devices. The Dexcom G6 Pro System can be used alone or in conjunction with these digitally connected medical devices for managing diabetes or assessing glycemic variability.

#### **C Special Conditions for Use Statement(s):**

Rx - For Prescription Use Only

#### **D Special Instrument Requirements:**

Not Applicable

### **IV Device/System Characteristics:**

#### **A Device Description:**

##### **G6 PRO 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 PRO 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. The transmitter includes an auto-start feature which enables the transmitter to start a session immediately upon attachment of the transmitter to the on-body wearable. The G6 Pro Transmitter can be used for retrospective CGM data logging and it can also send real-time estimated glucose values to a mobile application.

## G6 PRO MOBILE APP

The G6 CGM App for iOS and G6 CGM App for Android is the primary display system for the physician enabled, real-time users with a compatible, BLE-enabled smart device. The G6 CGM App is compatible with certain iOS, Android and Smart Device watches. A link to a list of compatible devices is included in the instructions for use.

The Dexcom G6 Pro 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 G6 Pro 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 then samples the electrical current produced by the sensor and converts these measurements into glucose readings using an onboard algorithm. The transmitter sends glucose data to the receiver and/or mobile app which displays the current glucose reading (updated every 5 minutes) and glucose trends (up to 12 hours) from the transmitter. The receiver and/or mobile app 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. The G6 Pro System does not require calibrations using self-monitoring of

blood glucose (SMBG), and the sensor life has an expected wear time of up to 10 days. The system can be used for either a real-time or retrospective CGM session. A users Healthcare Professional (HCP) elects which type of CGM session the patient uses (retrospective vs. real-time). The G6 Pro Transmitter Firmware supports a single-use 10-day sensor session per transmitter.

**C Instrument Description Information:**

<b>Modes of Operation</b>	<b>Yes</b>	<b>No</b>
Does the applicant’s device contain the ability to transmit data to a computer, webservice, or mobile device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does the applicant’s device transmit data to a computer, webservice, or mobile device using wireless transmission?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Software</b>		
FDA has reviewed applicant’s Hazard Analysis and software development processes for this line of product types.	<input checked="" type="checkbox"/>	<input type="checkbox"/>

1. Instrument Name:  
Dexcom G6 Pro Continuous Glucose Monitoring System
2. Specimen Identification:  
Not applicable.
3. Specimen Sampling and Handling:  
Not applicable.
4. Calibration:  
The Dexcom G6 Pro Continuous Glucose Monitoring System does not require user calibration, user calibration is not possible for this device.
5. Quality Control:  
Not applicable.

**V Substantial Equivalence Information:**

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

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

**C Comparison with Predicate(s):**

<b>Device &amp; Predicate Device(s):</b>	<u>K191450</u>	<u>K191833</u>
Device Trade Name	Dexcom G6 Continuous Glucose Monitoring (CGM) System	Dexcom G6 Pro Continuous Glucose Monitoring System
<b>General Device Characteristic Similarities</b>		
Intended Use	Intended to automatically measure glucose in bodily fluids continuously or frequently for a specified period of time. Designed to reliably and securely transmit glucose measurement data to digitally connected devices and 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
Data Presented	Estimated Glucose Value (EGV): The EGV is the nominal glucose value presented to the user. Glucose Trend: Based off the glucose rate of change, users are shown their glucose trend with a corresponding arrow. Historical Glucose Data: Users can view their previous three, six, twelve, or twenty-four hours of glucose data.	Same
Features	Connect to Dexcom Share: Users can share their glucose data with followers.	Same
Human Factors	Easy to understand UI/UX. Commonly understood navigation tools and features. Color-coded graphics.	Same

<b>General Device Characteristic Differences</b>		
Data Availability	Real-time	Real-time or retrospective at the discretion of a Healthcare Professional
Clinical application	Management of diabetes mellitus	Management of diabetes mellitus or assessing glycemic control in other conditions
Clinical setting/sites of use	Home use	Sensor insertion, transmitter attachment and retrospective glucose data download occurs in a clinic with a healthcare professional. Used at home in between clinic visits.
Transmitter Use Life	Reusable (90 days)	Single-Use (10-day)

## **VI Standards/Guidance Documents Referenced:**

ISO 13485:2003; Medical Devices-Quality management systems-Requirements for regulatory purposes

ISO 14971:2012; Medical devices – Applications of risk management to medical devices

IEC 62304, Ed. 1.1:2015; Medical Device Software – Software Lifecycle Processes (2006+AMD1:2015)

IEC 62366 Ed. 1.1:2014; Medical Devices – Application of usability engineering to medical devices, Edition 1.1 (2014)

IEC 60601-1:2005; Medical Electrical Equipment – Part 1: Requirements for basic safety and essential performance

ISO 15223-1:2012; Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

Guidance for Industry and FDA Staff, Format for Traditional and Abbreviated 510(k)s, dated August 2005

Guidance for Industry and FDA Staff, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, dated May 11, 2005

General Principles of Software Validation; Final Guidance for Industry and FDA Staff, dated January 11, 2002

Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff, dated October 2, 2014

Applying Human Factors and Usability Engineering to Medical Devices –Guidance for Industry and FDA Staff, dated February 3, 2016

Guidance for Industry and FDA Staff Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, dated November 30, 2004

eCopy Program for Medical Device Submissions, Guidance for Industry and FDA Staff, dated December 31, 2015

Refuse to Accept Policy for 510(k)s, dated January 30, 2018

## **VII Performance Characteristics (if/when applicable):**

The analytical and clinical performance of this device was established in K191450. The sensor and algorithm remain unchanged. The candidate transmitter has the same overall form, fit, and function as the predicate transmitter, the difference being updated transmitter firmware. Firmware was modified from K191450 to additionally support the storage of glucose data for the entire sensor wear period and enable retrospective analysis by a healthcare provider using an authorized extraction device. Transmitter firmware for the G6 pro is also updated to enable an auto-start feature, ensure only a single, ten-day use, and prevent calibration by the user. The predicate (K191450) mobile App (iOS and Android) has been updated to accommodate use by the candidate device.

### **A Analytical Performance:**

1. Precision/Reproducibility:

As established in K191450.

2. Linearity:

As established in K191450.

3. Analytical Specificity/Interference:

As established in K191450.

4. Assay Reportable Range:

As established in K191450.

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

As established in K191450.

6. Detection Limit:

As established in K191450.

7. Assay Cut-Off:

Not applicable.

8. Accuracy (Instrument):

As established in K191450.

9. Carry-Over:

Not applicable.

**B Comparison Studies:**

1. Method Comparison with Predicate Device:

Not applicable

2. Matrix Comparison:

Not applicable. Interstitial fluid is the only indicated matrix.

**C Clinical Studies:**

1. Clinical Performance:

As established in K191450.

2. Clinical Specificity:

As established in K191450.

**D Clinical Cut-Off:**

As established in K191450.

**E Expected Values/Reference Range:**

Not applicable.

**F Other Supportive Instrument Performance Characteristics Data:**

As established in K191450.

**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.