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

I Background Information:

A 510(k) Number

K234133

B Applicant

Dexcom Inc.

C Proprietary and Established Names

Dexcom G7 Continuous Glucose Monitoring System

D Regulatory Information

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

II Submission/Device Overview:

A Purpose for Submission:

Device change to add Watch app as an option for primary display for Apple users.

B Measurand:

Glucose 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 System (Dexcom G7 CGM System or G7) 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

In addition to the special conditions for use listed in the previous clearance for this system, the following special conditions for use are included specifically for the new Direct To Watch feature:

Watch app settings: The watch app uses settings from your phone app.

Bluetooth® wireless technology: Make sure your Bluetooth is on. If not, you won't get readings or alerts.

Make sure your 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.

Apple users must allow Location Permission and Critical Alerts to use the phone app.

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. The system is intended for single-patient use at home and requires a prescription.

The G7 System consists of the following primary components: a wearable, consisting of a G7 sensor and transmitter worn on the body and a display device, which can be a G7 Mobile Application (Mobile App) on an iOS or Android OS smart device or a G7 Receiver (Receiver). The G7 System uses Bluetooth Low Energy (BLE) for wireless communication between these components.

This submission introduces the Direct to Watch (DTW) feature for users who have a compatible Apple iPhone and Apple Watch. If users choose to enable this feature and the iPhone is not near their smartwatch, the user will be able to receive glucose data and alerts on the G7 Watch App (Watch App) directly from the transmitter. The DTW feature requires updates to the iOS Mobile App and Watch App, which are described in the sections below.

To achieve the intended functions and performance of the G7 System, one sensor and at least one display device (app or receiver) must be used together. The receiving device acts as the primary display device and the user may choose to use only the app (with optional DTW) or the receiver as the sole display device; they may also choose to use multiple display devices simultaneously. The user must pair the display device(s) with each unique sensor to enable communication and start a sensor session. During an active session, the sensor reports new 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 G7 System is unchanged from the predicate device, with the exception of the new direct to watch feature.

The G7 System comprises of the following subsystems:

- Glucose Sensing Subsystem (GSS): G7 Wearable (Sensor, Transmitter, and Patch) and Applicator
- Mobile Applications Subsystem (MAS): iOS and Android G7 Mobile Application (iOS App and Android App)
- Watch Application Subsystem (WAS): G7 Watch App (Watch App)
- Receiver Subsystem (RVS): G7 Receiver (Receiver)

Glucose Sensing Subsystem (GSS): G7 Wearable (Sensor, Transmitter, and Patch) and Applicator

The Sensor is a small and flexible wire inserted by the applicator into subcutaneous tissue where it converts glucose into electric current. The Transmitter is pre-connected to the sensor and is worn on the body by the adhesive patch. The Transmitter measures the electric current produced by the sensor and converts these measurements into estimated glucose values (EGV) using an onboard algorithm. The Transmitter is capable of sending glucose data to a display device (mobile app, receiver, or watch app).

Each GSS box also includes an overpatch, which is a general adhesive tape that helps with the adhesion of the wearable to the user's body.

Comparison to predicate device

The proposed G7 System uses the same GSS as the predicate device. There are no changes to the GSS as a result of this pre-market notification.

Mobile Applications Subsystem (MAS): iOS and Android G7 Mobile Application (iOS App and Android App)

The G7 Mobile App is available on both iOS and Android platforms for users with a compatible Bluetooth Low Energy (BLE)-enabled smart device. The Mobile App can be used as a primary display to receive and display glucose readings and trend graphs via BLE communication. The Mobile App provides in-app guidance for the user on how to apply and set up the wearable and how to create a user account. Once the set-up has been completed, the Mobile App receives information from the transmitter and acts as a user interface by indicating the system state (e.g., warm-up period, signal loss, etc.), displaying glucose readings and trend graphs, and alerting the user when glucose levels are outside of a target zone and when specific system states occur. The iOS App (Apple users) can also be used with the Watch Application Subsystem (WAS). When the user downloads the iOS Mobile App from the Apple App Store, they automatically download the Dexcom Watch App.

Comparison to predicate device

The G7 Mobile App (iOS app only) is being updated for the new feature introduced in this submission, referred to as the Direct to Watch (DTW). With DTW enabled, the user does not always need the phone to see CGM information on the smartwatch. The feature must be enabled and set up via the iOS App. With the new version of the G7 Mobile App, the user has the option to use the G7 Mobile App to turn on, onboard, and configure a Direct to Watch (DTW) feature, which subsequently allows the G7 Watch App to connect directly to the G7 Transmitter. All onboarding, details, and settings of the G7 Watch App are only viewable or configurable on the G7 Mobile App.

Watch Application Subsystem (WAS): G7 Watch App (Watch App)

Currently, users with compatible smartwatches can use the G7 Watch App to view glucose information and notifications, which are mirrored off of the phone iOS App (referred to as Standard Smartwatch mode). The Watch App is bundled as part of the iOS Mobile App software code and is by default automatically downloaded at the same time the user downloads their Mobile App from the Apple App Store.

Comparison to predicate device
The new DTW feature allows the Watch App to act as a primary display even when the iPhone is not in range of the wearable (sensor, transmitter). The Watch App can operate with either Direct to Watch (DTW) enabled (Direct to Watch mode) or DTW not enabled (Standard Smartwatch mode). DTW is the subject of this premarket notification. The two user experiences are described below:

- DTW Not Enabled (Standard Smartwatch mode) – this mode is identical to the Watch App included in the predicate device, where the Watch App connects to the G7 Mobile App and mirrors the G7 Mobile App UI. The user's smart phone is required to be within close proximity of the watch to utilize the Watch App, as the Watch App receives all information from the Mobile App.
- DTW Enabled (DTW mode) – this new smartwatch feature allows the Watch App to connect directly with the G7 Transmitter, after the sensor session has started and the user has enabled the DTW feature on their iOS App. This means that users are not required to keep their smart phones in close proximity to their Watch App in order to receive EGVs and alerts and can instead receive glucose data on their smartwatch directly from the Transmitter.

<u>Receiver Subsystem (RVS): G7 Receiver (Receiver)</u>
The Receiver is a small handheld device that can also be used as a primary display to receive and display glucose readings and trend graphs via BLE communication with the G7 Transmitter. Similar to the App, the Receiver can alert the user when glucose levels are outside of a target zone and when specific system states occur. The Receiver does not communicate directly with either the iOS App or the Watch App and is therefore not modified for the DTW feature.

Comparison to predicate device
The proposed G7 System uses the same Receiver Subsystem (RVS) as the predicate device. There are no changes to the RVS as a result of this pre-market notification.

B Principle of Operation:

The G7 CGM 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 display device for the user to see and use accordingly.

The principles of operation of the proposed G7 CGM System remain the same as the predicate.

C Instrument Description Information:

1. Instrument Name:

   Dexcom G7 Continuous Glucose Monitoring System

2. Specimen Identification:

   Not applicable

3. Specimen Sampling and Handling:

   Not applicable

4. Calibration:

   The G7 Continuous Glucose Monitoring System is factory calibrated and does not require a sensor code. User may enter optional calibration using fingerstick blood glucose values.

5. Quality Control:

   Not applicable

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

V Substantial Equivalence Information:

A Predicate Device Name(s):
Dexcom G7 Continuous Glucose Monitoring (CGM) System

B Predicate 510(k) Number(s):
K231081

C Comparison with Predicate(s):

Device & Predicate Device(s):	K234133	K231081
Device Trade Name	Dexcom G7 CGM System with DTW Feature	Dexcom G7 CGM System
General Device Characteristic Similarities		
Intended Use	An integrated continuous glucose monitoring system (iCGM) is intended to automatically measure glucose in bodily fluids continuously or frequently for a specified period of time. iCGM systems are designed to reliably and securely transmit glucose measurement data to digitally connected devices, including automated insulin dosing systems, and are intended to be used alone or in conjunction with these digitally connected medical devices for the purpose of managing a disease or condition related to glycemic control.	Same
Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via	Same

	glucose oxidase chemical reaction	
Compatibility with connected devices	Compatible with digitally connected devices, including automated insulin dosing (AID) systems	Same
Clinical Setting	Home use	Same
General Device Characteristic Differences		
Primary Display Device	Mobile App installed on compatible smart device or receiver. Apple users may also use Watch App	Mobile App installed on compatible smart device or receiver.

VI Standards/Guidance Documents Referenced:

N/A

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

The subject Decom G7 CGM System with DTW Feature is physically identical to the predicate Dexcom G7 CGM System except for the inclusion of the DTW feature. Therefore, all studies originally used to establish analytical and clinical performance of the G7 system in K213919 are leveraged for the subject device.

1. Precision/Reproducibility:

   Previously established in K213919.

2. Linearity:

   Previously established in K213919.

3. Analytical Specificity/Interference:

   Previously established in K213919.

4. Assay Reportable Range:

   See Linearity section above.

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

   Previously established in K213919.

6. Detection Limit:

   Previously established in K213919.

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.

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):

   Previously established in K213919.

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Not applicable

F Other Supportive Instrument Performance Characteristics Data:

Human Factors:
Dexcom employed a Human Factors Engineering/Usability Engineering (HFE/UE) process for the G7 Direct to Watch (DTW) feature, as described in FDA Guidance for Industry and Staff, titled, *Applying Human Factors and Usability Engineering to Medical Devices*, dated February 3, 2016 and IEC 62366-1:2015/A1:2020 titled, *Medical Devices – Part 1: Application of usability engineering to medical devices*.

Specific use scenarios and tasks the user would have to carry out correctly in order to use the device safely was identified. An analysis of hazards and risks was conducted on the Dexcom G7 CGM System with DTW Feature to determine safety risks associated with use of the system. All critical tasks for which a use error could lead to high severity of harm were evaluated with validation testing. Critical tasks were identified solely based on the severity of harm and included tasks resulting from known-use problems and hazards analysis.

Software Verification and Validation
Dexcom performed software verification and validation to ensure that the Dexcom G7 CGM System met the software requirements. Verification and validation of the software implementation is accomplished in accordance with applicable Dexcom procedures through software code review, unit testing, software verification testing, and system level integration testing. Results of the software executed protocols for the Dexcom G7 CGM System with DTW feature are acceptable for its intended use.

Cybersecurity:
Dexcom has provided cybersecurity risk management documentation for the System that includes an assessment of the assets, controls, threats, vulnerabilities, SBOM results, and penetration testing results of the system. The G7 System CRA report was completed in accordance with the FDA Guidance, "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*," dated September 27, 2023.

Wireless Coexistence:
The Dexcom G7 CGM System with DTW Feature underwent coexistence testing in the presence of common RF interfering signals that are likely to be encountered by users in a home environment. Wireless coexistence testing was performed to confirm the Dexcom G7 CGM with DTW Feature remains functional and performs within acceptable limits while in the presence of common radiating electronic devices in accordance with FDA Guidance "*Radio Frequency Wireless Technology in Medical Devices*," dated August 14, 2013.

Electrical Safety and Electromagnetic Compatibility:
The G7 CGM System with DTW Feature was assessed for and complies with the following standards regarding Electrical, Mechanical, and Thermal Safety (EMT) Testing: IEC 60601-1, IEC 60601-1-6, IEC 62366-1, IEC 60601-1-8, IEC 60601-1-11, EN 60529, and IEC 62304. As the DTW feature is a software specific change, all the EMT test results from the predicate device remain applicable. The Watch App software was assessed per IEC 62304:2006/AMD1:2015 and

complies with the standard.

Electromagnetic Compatibility (EMC) was performed to evaluate the G7 CGM System protection against electromagnetic disturbance and electromagnetic disturbance emitted by the G7 CGM System in compliance with IEC 60601-1-2:2014, IEC/TR 60601-4-2, and EN 301 489-17. The tests demonstrated that emissions produced by the CGM System are below acceptable limits to ensure protection of radio services and other equipment that could be in the vicinity of the CGM System, and that the ability of the CGM System in maintaining basic safety, essential performance, and performance related to its intended use was immune to reasonably foreseeable electromagnetic disturbances present in the home healthcare environment.

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.