510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K253737

B Applicant

Dexcom, Inc.

C Proprietary and Established Names

Dexcom G7 Continuous Glucose Monitoring (CGM) System,
Dexcom G7 15 Day 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

E Purpose for Submission:

Modifications to the adhesive patch

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

Dexcom G7 Continuous Glucose Monitoring System:

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.

Dexcom G7 15 Day Continuous Glucose Monitoring (CGM) System:

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

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

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

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Dexcom G7 Continuous Glucose Monitoring System:

• 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.

In addition to the special conditions listed above for the Dexcom G7 CGM system, the following special conditions for use were included specifically for the new Direct To Watch feature in K234133:

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.

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

III Device Description

The Dexcom G7 Continuous Glucose Monitoring System (G7 System) and the Dexcom G7 15 Day Continuous Glucose Monitoring System (G7 15 Day System) are interoperable continuous glucose monitoring (CGM) systems 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 is intended for persons with diabetes age 2 and older whereas the G7 15 Day System is intended for persons with diabetes age 18 and older.

The G7 System and G7 15 Day System consist 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 Application1 (Mobile App) on an iOS or Android OS smart device or a G7 Receiver (Receiver). The G7 System and G7 15 Day System use Bluetooth Low Energy (BLE) for wireless communication between these components.

To achieve the intended functions and performance of both the G7 System and the G7 15 Day 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 watch app) 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 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 both the G7 System and the G7 15 Day System is 40 g/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 for the G7 System and up to 15 days for the G7 15 Day System, both 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 proposed G7 System and G7 15 Day System are based on the same principle of operation and fundamental design as their respective predicate devices (K240902 and K243214) with identical user functionality, intended use, indications for use, display devices, sensor, and alerts/alarms.

The G7 System and G7 15 Day System comprise the following subsystems, which are described in comparison to the respective predicate below:

<u>Glucose Sensing Subsystem (GSS): Wearable (Sensor, Transmitter, and Patch) and Applicator</u>
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 (K240902 and K243214)
The proposed G7 System and the proposed G7 15 Day System include an alternate adhesive patch (MT-1000356). There are no changes to the Transmitter, Sensor or Applicator as a result of this premarket notification.

Alternate Adhesive Patch

Comparison of G7 System and G7 15 Day System Predicate Adhesive Patch and Proposed Adhesive Patch

Item	Subject Device (G7 and G7 15 Day)	Predicate (K240902 and k243214)
Adhesive Patch supplier and material	Solventum, Spunlace non-woven polyester acrylic adhesive with tackifier	Adhesives Research, NPU Acrylic adhesive

Mobile Applications: 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. When the user downloads the iOS Mobile App from the Apple App Store, the Dexcom Watch App is, by default, automatically downloaded.

Comparison to Predicate Device (K240902 and K243214)

The proposed G7 System and the proposed G7 15 Day System utilize the same G7 Mobile App, which is the same app as their respective predicate devices (K240902 and K243214). There are no changes to the G7 Mobile App as a result of this pre-market notification.

Watch Application: G7 Watch App (Watch App)

Users with compatible smartwatches can use the G7 Watch App to view glucose information and notifications. The Watch App is bundled as part of the iOS Mobile App software code and is automatically downloaded at the same time the user downloads their Mobile App from the Apple App Store. The Watch App operates in two modes:

- Standard Smartwatch mode – 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.
- Direct to Watch (DTW) mode – the Watch App connects 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.

Comparison to Predicate Device (K240902 and K243214)

The proposed G7 System and the proposed G7 15 Day System utilize the same G7 Watch App, which is the same app as their respective predicate devices (K240902 and K243214). There are no changes to the G7 Watch App as a result of this pre-market notification.

Receiver Subsystem (RVS): G7 Receiver (Receiver)
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 Transmitter. Similar to the Mobile App, the Receiver can alert the user when glucose levels are outside of a target zone and when specific system states occur.

Comparison to Predicate Device (K240902 and K243214)
The proposed G7 System and the proposed G7 15 day System use the same Receiver Subsystem (RVS) as their respective predicate devices (K240902 and K243214). There are no changes to the RVS as a result of this pre-market notification.

Interoperability
The GSS is designed to communicate to all display devices simultaneously. The proposed G7 System and the proposed G7 15 Day System, same as their respective predicate devices (K240902 and K243214), are also designed to communicate estimated glucose values, trend, and system information to other compatible electronic interfaces via the following secure wireless connections:

- Wireless communication from the transmitter directly to an interoperable device communicating through the same protocol
- The G7 Mobile App communicates to another app on a single mobile platform
- The G7 Mobile App communicates through the cloud to another software device.
- Dexcom Partner Web APIs: The Dexcom Partner Web APIs enable secure and reliable communication of CGM data to authorized client software intended to receive the data through the cloud. The Partner Web APIs is not intended to be used by automated insulin delivery systems (AID).

IV Substantial Equivalence Information:

A Predicate Device Name(s):

Dexcom G7 Continuous Glucose Monitoring System, Dexcom G7 15 Day Continuous Glucose Monitoring (CGM) System

B Predicate 510(k) Number(s):

K240902, K243214

C Comparison with Predicate(s):

Device & Predicate Device(s):	K253737	K240902	K243214
Device Trade Name	Dexcom G7 Continuous Glucose Monitoring (CGM) System Dexcom G7 15 Day Continuous Glucose Monitoring (CGM) System	Dexcom G7 CGM System	Dexcom G7 15 Day CGM System

General Device Characteristic Similarities			
Intended Use/Indications For Use	Dexcom G7 Continuous Glucose Monitoring (CGM) System: The Dexcom G7 Continuous Glucose Monitoring (CGM) 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. Dexcom G7 15 Day Continuous Glucose	The Dexcom G7 Continuous Glucose Monitoring (CGM) 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	The Dexcom G7 15 Day Continuous Glucose Monitoring (CGM) System (Dexcom G7 15 Day CGM System or G7 15 Day) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons 18 years and older. The Dexcom G7 15 Day CGM System is intended to replace fingerstick BG testing for diabetes treatment decisions. Interpretation of the Dexcom G7 15 Day CGM System results should be based on the glucose trends and several sequential sensor readings over time. The Dexcom G7 15 Day CGM System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments

	Monitoring (CGM) System: The Dexcom G7 15 Day Continuous Glucose Monitoring (CGM) System (Dexcom G7 15 Day CGM System or G7 15 Day) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons 18 years and older. The Dexcom G7 15 Day CGM System is intended to replace fingerstick BG testing for diabetes treatment decisions. Interpretation of the Dexcom G7 15 Day CGM System results should be based on the glucose trends and several sequential sensor readings over time. The Dexcom G7 15 Day CGM System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.	devices for the purpose of managing diabetes.	
Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction.	Same	Same
Compatibility with connected devices	Compatible with digitally connected devices, including automated insulin dosing (AID) systems	Same	Same
Measurement Range	40 - 400 mg/dL	Same	Same
General Device Characteristic Differences			
Adhesive Patch	Solventum, Spunlace non-woven polyester acrylic	Adhesives Research, NPU Acrylic adhesive	Adhesives Research, NPU Acrylic adhesive

	adhesive with tackifier		
Sensor Shelf-Life	18-months	18-months	12-months

V Standards/Guidance Documents Referenced:

- ISO 14971:2019, Medical devices - Application of Risk Management to Medical Devices
- ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-12:2021, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- AAMI TIR 28:2016, Product adoption and process equivalence for ethylene oxide sterilization
- ANSI AAMI ISO 11135:2014, Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices - Amendment 1: Revision of Annex E, Single batch release
- ANSI AAMI ISO 11737-2:2019, Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ANSI AAMI ISO 11737-1:2018, Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product [Including Amendment 1 (2021)]
- ISO 11138-1:2017, Sterilization of health care products - Biological indicators - Part 1: General requirements
- ISO 10993-2:2022, Biological Evaluation of medical devices - Part 2: Animal welfare requirements

VI Performance Characteristics:

A. Analytical Performance

1. Precision/Reproducibility:

   Previously established in K240902 and K243214.

2. Linearity:

   Previously established in K240902 and K243214.

3. Analytical Specificity/Interference:

   Previously established in K240902 and K243214.

4. Assay Reportable Range:

   Previously established in K240902 and K243214.

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

The Dexcom G7 sensor and transmitter have a storage shelf-life of up to 18 months. Shelf life was evaluated at 140°F. Sensors should be stored at 36°- 86°F and 10-90% relative humidity. Previously established in K243214 for the Dexcom G7 15 Day CGM System.

6. Detection Limit:

Previously established in K240902 and K243214.

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):

Sensor Life
A total of 210 sensors were evaluated to determine the percentage of sensors that lasted through the 15-day sensor life. Of the 210 Sensors, 81.9% of sensors lasted the full 15

days. No sensors were excluded from the sensor life evaluation. Three sensors were removed by the sponsor at the last scheduled clinic visit for the subject (censored from Kaplan Meier analysis). 32 sensors (15.2%) had "early sensor shut-off" (ESS), which is when a sensor automatically ends a sensor session as a result of self-diagnostics. One participant withdrew from the study and their sensor was censored on Day 7. 163 sensors survived past 15 days. Survival rates were calculated using the Kaplan Meier method.

An additional analysis of the survival study data was conducted to evaluate the survival rate for only the adhesive (i.e., considering only adhesive-related failures, such as when a sensor falls off). There were a total of 5 failures attributed to the adhesive. The 15-day survival rate for the adhesive (adhesive patch + overpatch) was 97.5%.

Sensor Survival Rate and Adhesive Survival Rate Over Wear Duration

Day of wear*	Number of sensors (n = 210)	Sensor survival rate(%)	Adhesive survival rate(%)
1	208	99.0	99.5
2	208	99.0	99.5
3	208	99.0	99.5
4	207	99.0	99.5
5	207	99.0	99.5
6	205	98.1	99.0
7	202	97.6	98.6
8	200	97.6	98.6
9	199	97.1	98.6
10	196	95.7	98.1
11	194	94.7	98.1
12	189	92.2	98.1
13	181	88.8	97.5
14	172	84.9	97.5
15	163	81.9	97.5

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

This same study was also used to evaluate the adhesive survival rate of the 10-day version of the G7 sensor in adults and pediatrics using the results observed through day 10. The adhesive survival rate through day 10 was 98.1% in adults and 100% in pediatrics (n=32 subjects, 2 years to 17 years old).

D. Clinical Cut-Off:

Not applicable.

E. Expected Values/Reference Range:

Not applicable.

F. Other Supportive Instrument Performance Characteristics Data

The following supportive performance characteristics were established through nonclinical

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

- Biocompatibility
- Sterilization Validation
- Packaging Validation

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

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

VII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

VIII Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.