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

I Background Information:

A 510(k) Number

K203089

B Applicant

Dexcom, Inc.

C Proprietary and Established Names

Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
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 previously cleared Dexcom G6 Glucose Program mobile app to allow the software module to be embedded into an authorized third-party host app. The software module does not allow fingerstick calibration which was optional in the predicate.

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

The Dexcom Glucose Program System is intended to replace fingerstick blood glucose testing for diabetes treatment 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 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 conjunction 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

The Dexcom Glucose Program System is intended for use in persons with diabetes who do not have a significant risk of hypoglycemia, therefore the 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.

The Dexcom Glucose Program System may not be appropriate for persons using intensive insulin therapy regimens (3 or more injections per day or insulin pump therapy), with hypoglycemia unawareness, and/or a documented history of severe hypoglycemic events.

Don’t wear your CGM (sensor, transmitter, or smartphone) for magnetic resonance imaging (MRI), computed tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment. The Dexcom Glucose Program System hasn’t been tested in those situations. Magnetic fields and heat could stop readings. Without readings, you might miss a low or high glucose event.

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.
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.

The user should follow the user manual instructions to ensure that all glucose values, and system alerts can be seen and heard. The smart phone and Bluetooth must be turned on and the program provider's app must always be running to ensure the user receives glucose values and system alerts. Set smart phone settings to allow Dexcom notifications to show on your Lock screen.

When using accessories with your smart phone such as headphones, Bluetooth speakers, or smart watch, keep in mind you may get system alerts on only one device or accessory, not all. After connecting any accessory devices, make sure that your smartphone's settings allow you to continue receiving system alerts.

Use your smartphone to get sensor glucose information while in the plane. After switching to airplane mode, turn your smartphone's Bluetooth on.

Before updating the smart device hardware or operating system, verify the compatibility of the updated hardware/software with the device system.

Sensor placement is important to ensure system performance. Users should choose a site that is:

- at least 3 inches from insulin pump infusion set or injection site or previous CGM insertion site
- away from waistband, scarring, tattoos, irritation, and bones
- unlikely to be bumped, pushed, or laid on while sleeping

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.

D Special Instrument Requirements:

Not applicable.

IV Device/System Characteristics:

A Device Description:

The Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) System is an interoperable connected device that can communicate glucose readings, trends, and other information wirelessly and securely to and from interoperable interfaces. The factory-calibrated system is intended for patients with diabetes who are not at significant risk of severe hypoglycemia.

System Components

The system consists of a sensor/applicator, a Bluetooth Low Energy (BLE) transmitter, and a BLE-enabled mobile CGM display.

Sensor: The sensor is a small and flexible wire, which is inserted by the applicator into subcutaneous tissue where it converts glucose into electrical current. The sensor may be worn for up to 10 days in the abdomen for adults, and both the abdomen and buttock for children ages 2-17 years old. The sensor is unchanged in this submission relative to the predicate.

Transmitter: The body-worn transmitter samples the electrical current produced by the sensor and converts these measurements into estimated glucose values (EGV) using an onboard algorithm. The transmitter sends glucose data to the mobile CGM display. The transmitter attaches to the sensor and can be re-used for multiple sensing sessions up to three months. The transmitter is unchanged in this submission relative to the predicate. The device is compatible with the transmitters cleared in K192787 and in K200876.

Applicable transmitter software versions in this submission include: G6 “Firefly” Transmitter Firmware (SW11818 version 2.18.2.98), G6 “Nuevo” Transmitter Firmware (SW12097 version 2.27.2.98).

Mobile display: A mobile app is designed to display the current glucose reading (updated every 5 minutes) as well as glucose trends. The mobile CGM display does not include any glucose-related alarm or alerts, but will alert the user when important system conditions occur such as an error state or when user input is needed.

Compatible Platforms

Please see user guides and Dexcom website for information on compatible mobile device platforms, operating systems, and host applications.

Proposed Change: Dexcom Zone App Module

The proposed Glucose Program System uses a new mobile CGM software module (app module) that is embedded within a compatible third-party mobile app (host app) and intended to serve as the primary display for the CGM system.

There is an Android app module and an iOS app module. The app module, referred to as Dexcom Zone, appears as a dedicated CGM tile within the host app.

The app module is designed as a protected software component with a fixed user interface and appearance that is run from a third-party host app and interacts directly with the smart device hardware/operating system. The module maintains the same core CGM functionality as the predicate device, independent of the host app. The app module was designed with architectural separation and data partitioning to ensure the non-CGM functions specific to the host app do not impact the safety or performance of the Dexcom CGM functions. The Dexcom app module's interface to the host app is limited to the following three functions: 1) start Dexcom app module; 2) coordinate CGM tile per Dexcom's specified display parameters; and 3) CGM user/account authentication. All CGM data is encrypted and stored in the Dexcom app module to prevent access or alteration of CGM data by the host app.

Similar to the predicate, the app includes the following functionality: sensor reading display, glucose trend, historical glucose data, time in range of target glucose, and system alerts (not glucose related).

The proposed app module does not include the following features, which were available in the predicate: share glucose data with up to three followers via the separate Follow app, chat feature, optional fingerstick calibration, data smoothing, time-in-range (TIR) low/high targets no longer configurable (fixed to 70/180 mg/dL), configurable trend graph height (fixed in app module to 40 – 300 mg/dL), configurable trend graph (fixed at 24 hours instead of choice of 6 or 12 hours), and widget/display enabling CGM reading (secondary display) and trend on notification panel.

B Principle of Operation:

The Dexcom Glucose Program System detects glucose levels from the fluid just beneath the skin (interstitial fluid). The sensor probe continuously measures glucose concentration in the interstitial fluid via an enzymatic electrochemical reaction using glucose oxidase. The enzyme, glucose oxidase, catalyzes the oxidation of glucose and produces hydrogen peroxide. The production of hydrogen peroxide generates an electrical current that is proportionate to the interstitial glucose concentration. The transmitter converts the signal using an algorithm to a glucose value read in mg/dL, which is then transmitted to the receiver/mobile application for the user to see and use accordingly.

C Instrument Description Information:

1. Instrument Name:

   Dexcom G6 Glucose Program Continuous Glucose Monitoring System

2. Specimen Identification:

   Not applicable.

3. Specimen Sampling and Handling:

   Not applicable.

4. Calibration:

   The Dexcom G6 Glucose Program Continuous Glucose Monitoring System in this submission is factory calibrated and does not allow manual calibration by the user.

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):

K200876

C Comparison with Predicate(s):

Device & Predicate Device(s):	K203089	K200876
Device Trade Name	Dexcom G6 Glucose Program Continuous Glucose Monitoring System	Same
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	Same

Device & Predicate Device(s):	K203089	K200876
	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.	
Clinical Application	Management of Diabetes mellitus	Same
Clinical setting/sites of use	Home use	Same
Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction	Same
Algorithm	Optimized Joint Probability Algorithm with improved data availability	Same
Compatibility with Intended Environments	Android OS and Apple iOS	Same
Transmitter	Welded transmitter only	Same
General Device Characteristic Differences		
CGM Display	Dexcom app module within the host app	Dexcom G6 Glucose Program System App
Calibration	Factory Calibrated only	Factory calibration with optional manual calibration
App Features	No Share Application	Share Application to share glucose data with followers
Compatible Program Host Apps	United Health Group (UHG) Level 2 App version 3.0.0	N/A

VI Standards/Guidance Documents Referenced:

Standards:

- ISO 13485:2016 Medical device - Quality management systems- Requirements for regulatory purposes
- ISO 14971:2012 Medical devices - Application of risk management to medical devices
- IEC 62304, Ed 1.1:2015 Medical Device Software - Software Lifecycle Processes (2006+ AMD I :2015)
- IEC 62366-1: 2015 Medical devices – Part 1: Application of usability engineering to medical devices
- ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- IEC 60601-1:2005 (Third Edition) Medical Electrical Equipment – Part 1: Requirements for basic safety and essential performance

Special Controls:

- 21 CFR 862.1355, integrated continuous glucose monitor.

FDA Guidance Documents:

- Guidance for Industry and FDA Staff, Format for Traditional and Abbreviated 510(k)s, dated September 13, 2019
- Guidance for Industry and FDA Staff, eCopy Program for Medical Device Submissions, dated December 13, 2019
- Guidance for Industry and FDA Staff, Refuse to Accept Policy for 510(k)s, dated September 13, 2019
- Guidance for Industry and FDA Staff, Multiple Function Device Products: Policy and Considerations, dated July 29, 2020
- Guidance for Industry and FDA Staff, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, dated May 11, 2005
- Final Guidance for Industry and FDA Staff, General Principles of Software Validation, dated January 11, 2002
- Guidance for Industry and Food and Drug Administration Staff, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, dated October 2, 2014

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Precision performance of the Dexcom G6 Glucose Program without additional calibration by the user was previously established in k200876.

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 VII.C.3 of the public decision summary for k200876.

3. Analytical Specificity/Interference:

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

4. Assay Reportable Range:

   See Linearity section above.

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

   As established in k200876.

6. Detection Limit:

   As established in k200876.

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.

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):
   See k200876.

D Clinical Cut-Off:
Not applicable.

E Expected Values/Reference Range:
Not applicable.

F Other Supportive Instrument Performance Characteristics Data:

Software Verification and Validation:

Software verification and validation is appropriate and the documentation provided is acceptable.

Cybersecurity:

The cybersecurity risk analysis is appropriate and the documentation provided is acceptable.

Interoperability:

The integration plan for the host app was found to be acceptable.

Human Factors:

The sponsor's assessment of usability-related risk is acceptable.

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

- Sterility
- Biocompatibility
- Mechanical Engineering
- Electromagnetic Compatibility
- Wireless
- Electrical Safety

- Environmental Testing
- Shelf-Life Stability
- Packaging Integrity/Shipping Integrity
- Contact Resistance

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.