



October 26, 2018

Dexcom, Inc.  
Luke Olson  
Senior Specialist, Regulatory Affairs  
6340 Sequence Dr.  
San Diego, CA 92121

Re: K182041

Trade/Device Name: Dexcom G6 Glucose Program Continuous Glucose Monitoring System  
Regulation Number: 21 CFR 862.1355  
Regulation Name: Integrated continuous glucose monitoring system  
Regulatory Class: Class II  
Product Code: QDK  
Dated: July 26, 2018  
Received: July 30, 2018

Dear Luke Olson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**Kellie B. Kelm -S**

for Courtney H. Lias, Ph.D.  
Director  
Division of Chemistry and Toxicology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

## Indications for Use

510(k) Number (if known)

K182041

Device Name

Dexcom G6 Glucose Program Continuous Glucose Monitoring System

Indications for Use (Describe)

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 age 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 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 conjunction with these digitally connected devices or services for the purpose of managing diabetes.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:     K182041    

### A. Submitter:

Dexcom, Inc.

6340 Sequence Dr.

San Diego, CA 92121

Contact: Luke Olson

Senior Regulatory Affairs Specialist

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Date Prepared:     October 24, 2018    

### B. Device Names and Classification:

<b>Proprietary Name</b>	Dexcom G6 Glucose Program Continuous Glucose Monitoring System
<b>Common Name</b>	Integrated Continuous Glucose Monitoring System, Factory Calibrated
<b>Class</b>	II
<b>Classification Regulation</b>	21 CFR 862.1355
<b>Product Code</b>	QDK
<b>Review Panel</b>	Clinical Chemistry

### C. Predicate Device:

Dexcom G6 Continuous Glucose Monitoring System (DEN170088)

### D. Device Description:

The Dexcom G6 Glucose Program Continuous Glucose Monitoring System (Dexcom Glucose Program System) is a continuous glucose monitor (CGM) that offers an altered feature set versus the predicate Dexcom G6 CGM System.

The Dexcom Glucose Program System consists of three main components: a sensor/applicator delivery system, a transmitter, and a mobile application (app). The sensor is a small and flexible wire inserted into subcutaneous tissue where it converts glucose into electrical current. The transmitter is connected to the sensor and is worn on the body. It 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 app. The app displays the current glucose reading (updated every 5 minutes) and glucose trends (up to 12 hours) from the transmitter. The app alerts users of important system conditions, when it enters an error state, or when requiring the user to enter information. The app also supports connectivity to Dexcom Share and Follow (DEN140016), however, the new app is a separate device from the Share and Follow apps.

**E. 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 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 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 digitally connected devices or services for the purpose of managing diabetes.

**F. Comparison with the Predicate Device:**

Device	Dexcom Glucose Program System (K182041)	Dexcom G6 CGM System (DEN170088)
<b>Trade Name</b>	Dexcom G6 Glucose Program Continuous Glucose Monitoring System	Dexcom G6 Continuous Glucose Monitoring System
<b>Manufacturer</b>	Dexcom, Inc.	Dexcom, Inc.
<b>Indications for Use</b>	The Dexcom G6 Glucose Program Continuous Glucose Monitoring System (Dexcom Glucose Program System) is a real time, continuous glucose monitoring device indicated	The Dexcom G6 Continuous Glucose Monitoring System (Dexcom G6 CGM System) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons age 2 years and older.

Device	Dexcom Glucose Program System (K182041)	Dexcom G6 CGM System (DEN170088)
	<p>for the management of diabetes in persons age 2 years and older.</p> <p>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.</p> <p>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 digitally connected devices or services for the purpose of managing diabetes.</p>	<p>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.</p> <p>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.</p>
<b>Clinical application</b>	Management of diabetes mellitus	Management of diabetes mellitus
<b>Clinical setting/sites of use</b>	Home use	Home use
<b>Principle of Operation</b>	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction
<b>Data Presented</b>	<p><b>Estimated Glucose Value (EGV):</b> The EGV is the nominal glucose value presented to the user.</p> <p><b>Glucose Trend:</b> Based off the glucose rate of change, users are shown their glucose trend with a corresponding arrow.</p> <p><b>Historical Glucose Data:</b> Users can view their previous six, or twelve</p>	<p><b>Estimated Glucose Value (EGV):</b> The EGV is the nominal glucose value presented to the user.</p> <p><b>Glucose Trend:</b> Based off the glucose rate of change, users are shown their glucose trend with a corresponding arrow.</p> <p><b>Historical Glucose Data:</b> Users can view their previous three, six, twelve, or twenty-four hours of glucose data.</p>

Device	Dexcom Glucose Program System (K182041)	Dexcom G6 CGM System (DEN170088)
	<p>hours of glucose data on a graph with high/low glucose thresholds.</p> <p><b>Time in Range:</b> Users can view the percent of time they spend in their target glucose range based on their configured high/low glucose thresholds.</p>	
<b>Features</b>	<p><b>Connect to Dexcom Share:</b> Users can share their glucose data with up to three followers.</p> <p><b>Chat with Wellness Coach:</b> Users can chat with a third-party wellness coach for encouragement, education, and motivation regarding their diabetes management.</p>	<p><b>Connect to Dexcom Share:</b> Users can share their glucose data with up to five followers.</p>
<b>Human Factors</b>	<p>Easy to understand UI/UX.</p> <p>Commonly understood navigation tools and features.</p> <p>Color-coded graphics.</p>	<p>Easy to understand UI/UX.</p> <p>Commonly understood navigation tools and features.</p> <p>Color-coded graphics.</p>
<b>Compatibility with intended environments</b>	<p>Compatible with the Samsung J3</p> <p>Compatible with Android OS version 7.0 and above</p>	<p>Compatible with iPhone 5S through iPhone X, Samsung Note 5, Note 8, Galaxy S6-S9, J3, Google Pixel, LG G5-G6</p> <p>Compatible with Android OS version 7.0 and above, and iOS version 10.3.2 and above</p>

## F. Summary of Performance Testing

The Dexcom Glucose Program System was verified and validated according to Dexcom’s internal design control process and in accordance with special controls for integrated continuous glucose monitors. This testing demonstrated that the system performed according to its specifications and that the technological and performance criteria are comparable to the predicate device.

## G. Conclusions Drawn from Performance Testing

The Dexcom Glucose Program System is substantially equivalent to the Dexcom G6 Continuous Glucose Monitoring System as they are identical with regard to intended use and there are no differences in technological characteristics that raise different questions of safety and effectiveness. The Dexcom Glucose Program System provides a feature set

designed to help persons who are not at significant risk of severe hypoglycemia manage their diabetes.