August 17, 2021

Dexcom, Inc.
Bryan Osborne
Senior Regulatory Affairs Specialist
6340 Sequence Dr.
San Diego, California 92121

Re: K203089
Trade/Device Name: Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) System
Regulation Number: 21 CFR 862.1355
Regulation Name: Integrated continuous glucose monitoring system
Regulatory Class: Class II
Product Code: QDK
Dated: March 5, 2021
Received: March 8, 2021

Dear Bryan Osborne:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K203089

Device Name
Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) 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 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.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 5 510(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: K203089

## 5.1 SUBMITTER:

Dexcom, Inc.
6340 Sequence Dr.
San Diego, CA 92121

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Date Prepared: July 19, 2021

## 5.2 DEVICE NAMES AND CLASSIFICATION:

| | |
|---|---|
| **Proprietary Name** | Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) System |
| **Common Name** | Integrated Continuous Glucose Monitoring System, Factory Calibrated |
| **Class** | II |
| **Classification Regulation** | 21 CFR 862.1355 |
| **Product Code** | QDK |

| | |
|---|---|
| **Review Panel** | Clinical Chemistry |

## 5.3 PREDICATE DEVICE:

Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) System (K200876)

## 5.4 DEVICE DESCRIPTION:

The Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) System measures and displays glucose values and trends for patients with diabetes who are not at significant risk of severe hypoglycemia. The system is factory calibrated and provides continuous glucose readings at five-minute intervals for up to ten days of use. The system consists of a sensor/applicator, a Bluetooth Low Energy (BLE) transmitter, and a BLE enabled mobile CGM display.

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 transmitter is connected to the sensor and is worn on the body. The 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, which displays the current glucose reading (updated every 5 minutes) and 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.

The subject of this submission is a change to the primary display mobile device software. Compared to the predicate device which uses a standalone mobile CGM application, the proposed Glucose Program System uses a new mobile CGM software module (app module) that is embedded within a third party program provider's mobile app (host app).

This change is to help encourage CGM retention for those not at significant risk of severe hypoglycemia by providing Dexcom Glucose Program CGM functions and program provider's functions on a single unified mobile application. The app module is designed as a finished sovereign software that interacts directly with smart device hardware/operating system and maintains the same core CGM functionality as the predicate device, independent of the host app. The proposed Glucose Program System uses the same sensor/applicator and transmitter as the predicate device, with only changes to the mobile CGM software.

The change to the primary display mobile device software described in this submission does not impact the standalone G6 mobile application used in the G6 CGM System (last cleared K200876) and only affects the Glucose Program System which is designed for payor-sponsored, value-based health programs.

## 5.5 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 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.

## 5.6 COMPARISON WITH THE PREDICATE DEVICE:

| Device | Dexcom G6 Glucose Program System (K200876, Predicate) | Dexcom G6 Glucose Program System (subject device) |
|---|---|---|
| **Trade Name** | Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) System | **Same** |
| **Manufacturer** | Dexcom, Inc. | **Same** |
| **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** |
| **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 | **Same** |

| Device | Dexcom G6 Glucose Program System (K200876, Predicate) | Dexcom G6 Glucose Program System (subject device) |
|---|---|---|
| | for the management of diabetes in persons age 2 years and older.<br><br>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.<br><br>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. | |
| **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** |

| Device | Dexcom G6 Glucose Program System (K200876, Predicate) | Dexcom G6 Glucose Program System (subject device) |
|---|---|---|
| **System Components** | Sensor/Applicator, Transmitter, Display Device (mobile app) | **Substantially Equivalent** with no adverse impact on safety or effectiveness.<br><br>The proposed Dexcom G6 Glucose Program CGM System uses the same Sensor/Applicator and Transmitter as the predicate device while introducing an alternative primary display CGM software. The proposed G6 Glucose Program System uses a new mobile CGM software module (app module) that is embedded within a third-party program provider's mobile app (host app) to provide patients both CGM functions and the program provider's functions on a single unified mobile application. The proposed G6 Glucose Program app module has the same core CGM functionality and meets the same system requirements as the predicate G6 Glucose Program System. |
| **Data Presented** | Estimated Glucose Value (EGV): The EGV is the nominal glucose value presented to the user.<br>Glucose Trend: Based off the glucose rate of change, users are shown their glucose trend with a corresponding arrow.<br>Historical Glucose Data: Users can view their previous six, or twelve hours of glucose data on a graph with high/low glucose thresholds.<br>Time in Range**:** Users can view the percent of time they spend in their target glucose range based on their configured high/low glucose thresholds. | **Substantially equivalent** with no adverse impact on safety or effectiveness.<br><br>The proposed Glucose Program System maintains the same key features as the predicate device, including EGV, glucose trend, historical glucose data, and time in range of target glucose. The proposed system includes modifications to the graphical user interface trend graph layout, symbols used to show glucose rate of change (i.e. trend arrows), and general app layout/navigation. There is no impact to rate of change based on provided trend arrows. These changes do not significantly impact safety or effectiveness of the Glucose Program System and its intended population. |
| **Transmitter** | G6 Welded (Nuevo) Transmitter | **Same** |

| Device | Dexcom G6 Glucose Program System (K200876, Predicate) | Dexcom G6 Glucose Program System (subject device) |
|---|---|---|
| **Glucose Value Estimation Algorithm** | Optimized Joint Probability Algorithm with improved data availability | **Same** |
| **Factory Calibration** | Yes | **Same** |
| **Optional Calibration** | Yes | **Substantially equivalent** with no adverse impact on safety or effectiveness.<br><br>No impact to clinical validation. The accuracy of the Factory Calibrated G6 CGM System was demonstrated to meet the iCGM (21 CFR 862.1355) Special Controls requirements in DEN170088. The predicate and proposed Glucose Program Systems use the same sensor and transmitter as the G6 CGM System. The Optional SMBG Calibration feature was removed to simplify user experience. |
| **Features** | Connect to Dexcom Share: Users can share their glucose data with up to three followers.<br>Chat with Wellness Coach: Users can chat with a third-party wellness coach for encouragement, education, and motivation regarding their diabetes. | **Substantially equivalent** with no adverse impact on safety or effectiveness.<br><br>Removed Share/Follow and third-party wellness coach chat features from the proposed device. Chat feature can still be accessed through the host app. Changes do not significantly impact safety or effectiveness and its intended population. |
| **Human Factors** | Easy to understand user interface and user experience. Commonly understood navigation tools and features. Color-coded graphics. | **Substantially equivalent** with no adverse impact on safety or effectiveness.<br><br>Changes to the primary display mobile device software user interface and workflow do not contribute to any safety-critical risks or impact any previously validated mitigations for the G6 Glucose Program CGM System. |
| **Alerts** | Autonomous Detection and Notification:<br><br>Signal Loss (not configurable)<br><br>Sensor Failure (not configurable)<br><br>Transmitter Failure (not configurable) | **Same** |

| Device | Dexcom G6 Glucose Program System (K200876, Predicate) | Dexcom G6 Glucose Program System (subject device) |
|---|---|---|
| **Compatibility with intended environments** | Compatible with Android OS version 7.0 and above and iOS version 13.2 and above. | **Substantially equivalent** with no adverse impact on safety or effectiveness.<br><br>Dexcom qualifies mobile device operating systems using the same performance/ acceptance criteria as the predicate device. |

## 5.7 TECHNOLOGY CHARACTERISTICS

The proposed Dexcom Glucose Program System is used to measure glucose values via amperometric measurement of current proportional to glucose concentration in interstitial fluid via a glucose oxidase chemical reaction. The proposed Dexcom Glucose Program System shares the same technological characteristics as the predicate device (K200876). The proposed Dexcom Glucose Program System adds a modified CGM app software solution that is embedded in a third party's iOS and Android 'host-app' for an improved single-app patient experience.

## 5.8 SUMMARY OF PERFORMANCE TESTING

The proposed Dexcom Glucose Program System was verified and validated according to Dexcom's internal design control process. All testing referenced in the predicate device (K200876) in accordance with special controls for integrated continuous glucose monitors remain applicable. The proposed system uses the same transmitter hardware and software requirements/design specifications as the predicate device. Therefore, performance testing and software verification and validation testing for the transmitter referenced in the predicate device (K200876) remains applicable. Software testing was completed to ensure all requirements of the proposed iOS and Android app modules are fulfilled while operating in the final host-app configuration.

## 5.9 CONCLUSIONS

The proposed Dexcom G6 Glucose Program CGM System and predicate Dexcom G6 Glucose Program CGM System (K200876) are identical with regard to intended use, indications for use, fundamental scientific technology, and principle of operation. The proposed system is substantially equivalent to the predicate device with regard to mobile software functionality, graphical user interface, and feature set. The proposed Glucose Program System CGM display is substantially equivalent to the predicate device as the proposed change does not raise any new questions of safety or effectiveness.