October 25, 2019

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

Re: K192787
Trade/Device Name: Dexcom G6 Glucose Program Continuous Glucose Monitoring (GCM) System
Regulation Number: 21 CFR 862.1355
Regulation Name: Integrated continuous glucose monitoring system
Regulatory Class: Class II
Product Code: QDK
Dated: September 26, 2019
Received: September 30, 2019

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,

Kellie B. Kelm, Ph.D.
Acting 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K192787

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 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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# SECTION 6 510(K) SUMMARY

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

The assigned 510(k) number is: K192787

## 6.1 SUBMITTER:


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

Contact: Bryan Osborne
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Date Prepared: September 26, 2019

## 6.2 DEVICE NAMES AND CLASSIFICATION:

| Predicate Device | |
|---|---|
| **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 |

## 6.3 PREDICATE DEVICE:

Dexcom G6 Glucose Program Continuous Glucose Monitoring System (K191450)

## 6.4 DEVICE DESCRIPTION:

### 6.4.1 Dexcom G6 Glucose Program Continuous Glucose Monitoring 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 it requires the user to enter information. The app also supports connectivity to Dexcom Share and Follow mobile application.

The proposed Dexcom G6 Glucose Program System is based on the same physical principles and fundamental design as the predicate system but includes an alternative, ultrasonic-welded transmitter. The transmitter attaches to the sensor wearable which is adhered to the user's body. The Dexcom G6 Glucose Program System is designed to function as intended with either the proposed or predicate transmitter (K191450). The proposed transmitter has the same form, fit, and function as the predicate transmitter (K191450) and, from the users' perspective, functions identically.

## 6.5 INDICATIONS FOR USE

### 6.5.1 Dexcom G6 Glucose Program Continuous Glucose Monitoring System

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.

## 6.6 COMPARISON WITH THE PREDICATE DEVICE:

### 6.6.1 Dexcom G6 Glucose Program Continuous Glucose Monitoring System

| Device | Dexcom G6 Glucose Program System (predicate device; K191450) | 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 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 | Same |

| Device | Dexcom G6 Glucose Program System (predicate device; K191450) | Dexcom G6 Glucose Program System (subject device) |
|---|---|---|
| | 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 |
| **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. | Same |
| **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 management. | Same |
| **Human Factors** | Easy to understand UI/UX. | Same |

| Device | Dexcom G6 Glucose Program System (predicate device; K191450) | Dexcom G6 Glucose Program System (subject device) |
|---|---|---|
| | Commonly understood navigation tools and features.<br>Color-coded graphics. | |
| **Compatibility with intended environments** | Compatible with Android OS version 7.0 and above | Same |
| **Transmitter** | G6 (Epoxy) Transmitter only | G6 (Epoxy) Transmitter *and G6 (Welded) Transmitter* |

## 6.7 TECHNOLOGICAL CHARACTERISTICS

The proposed Dexcom G6 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 G6 Glucose Program System shares the same technological characteristics as the predicate device (K191450).

## 6.8 SUMMARY OF PERFORMANCE TESTING

The proposed Dexcom G6 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. Performance testing and software verification and validation testing was completed for the proposed transmitter. To validate the design of the proposed transmitter firmware with the predicate Glucose Program Mobile App, system integration testing was completed to ensure system level and display requirements remain fulfilled.

## 6.9 CONCLUSIONS

The proposed Dexcom G6 Glucose Program System is substantially equivalent to the predicate Dexcom G6 Glucose Program System as it shares the same intended use, indications for use, as well as technological characteristics. Further, the proposed change does not raise different questions of safety and effectiveness.