February 14, 2019

Dexcom, Inc.
Bryan Osborne
Specialist II, Regulatory Affairs
6310 Sequence Dr.
San Diego, CA 92121

Re: K183206
Trade/Device Name: Dexcom G6 Continuous Glucose Monitoring System
Regulation Number: 21 CFR 862.1355
Regulation Name: Integrated continuous glucose monitoring system
Regulatory Class: Class II
Product Code: QBJ
Dated: November 16, 2018
Received: November 19, 2018

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/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) 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

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)*
k183206

Device Name
Dexcom G6 Continuous Glucose Monitoring System

Indications for Use *(Describe)*
The Dexcom G6 Continuous Glucose Monitoring System (Dexcom G6 System) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons age 2 years and older.

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.

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.

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."*

# 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: k183206

## 5.1 SUBMITTER:

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

Contact: Bryan Osborne

Specialist, Regulatory Affairs

Phone: 858.875.9896

Fax: 858.332.0204

Email: bosborne@dexcom.com

Date Prepared: February 12, 2019

## 5.2 DEVICE NAMES AND CLASSIFICATION:

| | |
|---|---|
| **Proprietary Name** | Dexcom G6 Continuous Glucose Monitoring System |
| **Common Name** | Integrated Continuous Glucose Monitoring System, Factory Calibrated |
| **Class** | II |
| **Classification Regulation** | 21 CFR 862.1355 |
| **Product Code** | QBJ |
| **Review Panel** | Clinical Chemistry |

## 5.3 PREDICATE DEVICE:

Dexcom G6 Continuous Glucose Monitoring System (DEN170088)

## 5.4 DEVICE DESCRIPTION:

The Dexcom G6 Continuous Glucose Monitoring System consists of three main components: a sensor, a Bluetooth Low Energy (BLE) transmitter, and a BLE enabled display device (receiver and/or mobile 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 receiver and/or mobile app which displays the current glucose reading (updated every 5 minutes) and glucose trends (up to 12 hours) from the transmitter. The Dexcom G6 System does not require calibrations using SMBG, and the sensor life has an expected wear time of up to 10 days. The receiver and/or mobile app displays the current glucose reading and glucose trends to the user. It alerts the user when glucose levels are outside of a target zone and when other important system conditions occur.

The Dexcom G6 sensor, algorithm, receiver, and app remain unchanged, with modifications to the design of the transmitter. The proposed Dexcom G6 System is based on the same physical principles and fundamental design as the commercially-available Dexcom G6 System (DEN170088), but has modifications to physical design, software, and hardware of the transmitter. The Dexcom G6 System is designed to function as intended with either the proposed, or current G6 transmitter. The proposed G6 transmitter has the same form, fit, and function as the commercial G6 transmitter and, from the users' perspective, functions identically.

## 5.5 COMPARISON WITH THE PREDICATE DEVICE:

| Device | Dexcom G6 CGM System (subject device) | Dexcom G6 CGM System (DEN170088) |
|---|---|---|
| **Trade Name** | Dexcom G6 Continuous Glucose Monitoring System | Dexcom G6 Continuous Glucose Monitoring System |
| **Manufacturer** | Dexcom, Inc. | Dexcom, Inc. |
| **Indications for Use** | The Dexcom G6 Continuous Glucose Monitoring System (Dexcom G6 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 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.<br><br>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. | The Dexcom G6 Continuous Glucose Monitoring System (Dexcom G6 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 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.<br><br>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. |
| **Clinical application** | Management of diabetes mellitus | Management of diabetes mellitus |
| **Clinical setting/sites of use** | Home use | Home use |
| **Principle of Operation** | 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 |

| Device | Dexcom G6 CGM System (subject device) | Dexcom G6 CGM System (DEN170088) |
|---|---|---|
| **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 three, six, twelve, or twenty-four hours of glucose data. | **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 three, six, twelve, or twenty-four hours of glucose data. |
| **Features** | **Connect to Dexcom Share:** Users can share their glucose data with up to five followers. | **Connect to Dexcom Share:** Users can share their glucose data with up to five followers. |
| **Human Factors** | Easy to understand UI/UX.<br>Commonly understood navigation tools and features.<br>Color-coded graphics. | Easy to understand UI/UX.<br>Commonly understood navigation tools and features.<br>Color-coded graphics. |
| **Compatibility with intended environments** | iPhone 4S- iPhone X, Google Pixel, Google Pixel 2, Samsung Galaxy Note 5, Samsung Galaxy Note 8, Samsung Galaxy S6, Samsung Galaxy S6 Edge, Samsung Galaxy S7, Samsung Galaxy S7 Edge, Samsung Galaxy S8, Samsung Galaxy S8 Plus, Samsung Galaxy S9, Samsung Galaxy S9+, Samsung Galaxy J3 [SM-J327 models only, including J3 Eclipse, J3 Emerge, J3 Prime, Express Prime 2, Amp Prime 2], LG G5, LG G6<br><br>Compatible with Android OS version 7.0 and above, and iOS version 10.3.2 and above | iPhone 4S- iPhone X, Google Pixel, Google Pixel 2, Samsung Galaxy Note 5, Samsung Galaxy Note 8, Samsung Galaxy S6, Samsung Galaxy S6 Edge, Samsung Galaxy S7, Samsung Galaxy S7 Edge, Samsung Galaxy S8, Samsung Galaxy S8 Plus, Samsung Galaxy S9, Samsung Galaxy S9+, Samsung Galaxy J3 [SM-J327 models only, including J3 Eclipse, J3 Emerge, J3 Prime, Express Prime 2, Amp Prime 2], LG G5, LG G6<br><br>Compatible with Android OS version 7.0 and above, and iOS version 10.3.2 and above |

## 5.6 SUMMARY OF PERFORMANCE TESTING

The proposed Dexcom G6 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.

## 5.7 CONCLUSIONS DRAWN FROM PERFORMANCE TESTING

The proposed Dexcom G6 Continuous Glucose Monitoring System is substantially equivalent to the predicate Dexcom G6 System as they are identical with regard to intended use, indications for use, and there are no differences in technological characteristics that raise different questions of safety and effectiveness. The proposed Dexcom G6 Continuous Glucose Monitoring System provides an alternative transmitter for the manufacture (Dexcom, Inc.) that meets all required performance criteria for the predicate Dexcom G6 System.