July 15, 2021

Dexcom, Inc.
Maryam Amini
Staff Regulatory Affairs Specialist
6310 Sequence Dr.
San Diego, California 92121

Re: K201328
Trade/Device Name: Dexcom G6 Continuous Glucose Monitoring (CGM) System
Regulation Number: 21 CFR 862.1355
Regulation Name: Integrated continuous glucose monitoring system
Regulatory Class: Class II
Product Code: QBJ
Dated: October 7, 2020
Received: October 8, 2020

Dear Maryam Amini:

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)*
K201328

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.

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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: K201328

5.1 SUBMITTER:

Dexcom, Inc.
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Date Prepared: July 14, 2021

5.2 DEVICE NAMES AND CLASSIFICATION:

Proprietary Name	Dexcom G6 Continuous Glucose Monitoring (CGM) 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 (CGM) System (K200876)

5.4 DEVICE DESCRIPTION:

The Dexcom G6 Continuous Glucose Monitoring System (G6 System) is an interoperable connected device that measures and displays glucose values for patients with diabetes. The G6 System consists of three main components: a sensor/applicator, a Bluetooth Low Energy (BLE) transmitter, and a BLE enabled display device (receiver and/or mobile application). 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 has an expected wear time of up to 10 days. 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 receiver and/or mobile app, which displays the current glucose reading (updated every 5 minutes) and glucose trends. The receiver and/or mobile app also alerts the user when glucose levels are outside of a target zone and when other important system conditions occur. The G6 System is designed to be used alone or in conjunction with digitally connected devices. The G6 System can communicate Estimated Glucose Values (EGV) and other information wirelessly and securely to and from these digitally connected devices in several ways, such as described below:

1. Wireless communication from the transmitter directly to an interoperable device communicating through the same protocol.
2. The app communicates to another app on a single mobile platform.
3. The app communicates through the cloud to another software device.

The proposed G6 CGM System is based on the same physical principles and fundamental design as the commercially available G6 CGM System (K200876), but it includes an additional software component.

The added software component, which consists of cloud-based Application Programming Interfaces (APIs), is identified as Dexcom Partner Web APIs (Partner Web APIs). The Partner Web APIs enables communication of iCGM data to client software intended to receive the data through the cloud. The transmitted data can be used by authorized client software for specific and permitted use cases including non-medical device application, medical device data analysis, CGM secondary display alarm, active patient monitoring, and treatment decisions. The software application may not be used in environments not currently cleared for Dexcom G6 CGM System (e.g. hospital for inpatient care). The Partner Web APIs is not intended to be used by automated insulin delivery systems (AID).

Dexcom display devices (receiver and mobile app) continues to serve as a primary display device for the (iCGM) data, which directly receives the data from the transmitter. Identical

to the G6 CGM System cleared in K200876, the mobile app includes a design mitigation that overrides Do Not Disturb settings on the smart device with the users' consent. With this app design mitigation, the G6 CGM system functions as intended to provide users with critical alarm and alerts (e.g. Urgent Low alarm) regardless of the user's smart device settings for Do Not Disturb. The current components of the Dexcom G6 System (sensor/applicator, transmitter, and display devices) have not been changed as a result of the added Partner Web APIs.

5.5 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.

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.

5.6 COMPARISON WITH THE PREDICATE DEVICE:

Device	**Dexcom G6 CGM System (K200876, Predicate)**	**Dexcom G6 CGM System (subject device)**
Trade Name	Dexcom G6 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	**Same**

Device	Dexcom G6 CGM System (K200876, Predicate)	Dexcom G6 CGM System (subject device)
	connected medical devices for the purpose of managing a disease or condition related to glycemic control.	
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. 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.	**Same**
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 CGM System (K200876, Predicate)	Dexcom G6 CGM System (subject device)
Data Presented	Estimated Glucose Value (EGV): The EGV is the nominal glucose value presented to the user. Glucose Trend: Based off the glucose rate of change, users are shown their glucose trend with a corresponding arrow. Historical Glucose Data**:** Users can view their previous three, six, twelve, or twenty-four hours of glucose data.	**Same**
Features	Connect to Dexcom Share: Users can share their glucose data with followers.	**Substantially Equivalent** with no adverse impact on safety or effectiveness. Users can share their glucose data with client software in addition to their followers. An interoperability communication plan will be provided to potential partners/developers. This interoperability communication plan specifies expectations, requirements and interface specifications to ensure the data is transmitted and received securely and reliably by the digitally connected devices. Dexcom conducted software verification to ensure predefined requirements including but not limited to data confidentiality, integrity, and timely availability were fulfilled.

Device	Dexcom G6 CGM System (K200876, Predicate)	Dexcom G6 CGM System (subject device)
Interoperability	Designed to communicate with interoperable devices in several ways, such as described below: • Wireless communication from the transmitter directly to an interoperable device communicating through the same protocol. • The app communicates to another app on a single mobile platform. • The app communicates through the cloud to another software device.	**Substantially Equivalent** with no adverse impact on safety or effectiveness. The G6 System can now also communicate iCGM data wirelessly and securely to and from digitally connected devices (client software) through a cloud-based communication method, Partner Web APIs. An interoperability communication plan will be provided to potential partners/developers. This interoperability communication plan specifies expectations, requirements and interface specifications to ensure the data is transmitted and received securely and reliably by the digitally connected devices. Dexcom conducted software verification to ensure predefined requirements including but not limited to data confidentiality, integrity, and timely availability were fulfilled.
Human Factors	Easy to understand UI/UX. Commonly understood navigation tools and features. Color-coded graphics.	**Same**
Compatibility with intended environments	Android OS and Apple iOS	**Same**

5.7 TECHNOLOGY CHARACTERISTICS

The proposed Dexcom G6 CGM System has the same technological characteristics as its predicate (K200876), which is used to measure glucose values via an amperometric measurement of current proportional to glucose concentration in interstitial fluid via a glucose oxidase chemical reaction. The proposed Dexcom G6 CGM System can communicate with authorized client software for specific and permitted use cases in the currently cleared intended use environments.

5.8 SUMMARY OF PERFORMANCE TESTING

The proposed Dexcom G6 CGM System was verified according to Dexcom's internal design control process and in accordance with special controls for integrated continuous glucose

monitoring system. This testing demonstrated that the proposed system performed according to its specifications, and the proposed system have met its technological and performance criteria, which have not changed from the predicate device (K200876).

5.9 CONCLUSIONS

The information provided in this premarket notification support that the proposed Dexcom G6 CGM System is substantially equivalent to its predicate as they are identical with regard to intended use and indications for use and there are no differences in technological characteristics that raise different questions of safety and effectiveness.