December 4, 2020

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

Re: K200876
Trade/Device Name: Dexcom G6 Continuous Glucose Monitoring System
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: QBJ, QDK
Dated: November 3, 2020
Received: November 5, 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,

Kellie B. Kelm, Ph.D.
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)*
K200876

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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)*
K200876

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.

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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: K200876

5.1 SUBMITTER:

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

Contact: Maryam Amini
Staff Regulatory Affairs Specialist
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Date Prepared: December 01, 2020

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

Proprietary Name	Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) System
Class	II
Classification Regulation	21 CFR 862.1355
Product Code	QDK

5.3 PREDICATE DEVICE:

Dexcom G6 Continuous Glucose Monitoring (CGM) System (K191450)

Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) System (K191450)

5.4 DEVICE DESCRIPTION:

5.4.1 Dexcom G6 Continuous Glucose Monitoring (CGM) System

The Dexcom G6 Continuous Glucose Monitoring (CGM) 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 app). The sensor is a small and flexible wire 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. It 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 alerts the user when glucose levels are outside of a target zone and when other important system conditions occur. The G6 sensor life has an expected wear time of up to 10 days. Though the Dexcom G6 CGM System is factory calibrated and does not require user calibration, users of the Dexcom G6 CGM System have the option to calibrate the device (e.g., in situations where users do not have to use the sensor code). When operating in factory calibration mode (using sensor code, the primary mode of G6 CGM System), the G6 algorithm does not require SMBG calibration and instead uses sensor glucose sensitivity estimates determined during manufacturing for EGV calculation. When operating in manual calibration mode (no sensor code), the G6 algorithm relies on daily SMBG calibrations and time-matched sensor counts (matched pairs) to estimate calibration parameters for EGV calculation. When a SMBG calibration is entered into the system (in either mode), this information may be used by the system for estimating the glucose using the Bayesian Joint probability algorithm (JPA).

The proposed G6 CGM System is based on the same physical principles and fundamental design as the commercially available G6 CGM System (K191450), but it includes a modified algorithm (onboard algorithm) in the welded version of the G6 Transmitter (also named “Firefly” Transmitter in Dexcom’s internal documents). The proposed algorithm is modified to improve data availability by modifications to modules that handle noise events and calibrations when applicable. Additionally, the algorithm has been modified to improve detectability of sensors approaching end of life. Except the modified transmitter firmware, there have been no changes to other components of the G6 CGM System (sensor/applicator, transmitter hardware, receiver, and mobile app) introduced by the modified algorithm.

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

The Dexcom G6 Glucose Program CGM System consists of three main components: the sensor/applicator delivery system, transmitter, and 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. 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. The G6 sensor life has an expected wear time of up to 10 days. Though the Dexcom G6 Glucose Program CGM System is factory calibrated and does not require user calibration, users have the option to calibrate the device when operating in factory calibration mode (using sensor code, the only mode of System). When a SMBG calibration is entered into the system, this information may be used by the system for estimating the glucose using the Bayesian Joint probability algorithm (JPA).

The proposed G6 Glucose Program CGM System is based on the same physical principles and fundamental design as the commercially available G6 Glucose Program CGM System, but it includes a modified algorithm (onboard algorithm) in the welded version of the G6 Transmitter (also named “Firefly” Transmitter in Dexcom’s internal documents). The proposed algorithm is modified to improve data availability by modifications to modules that handle noise events and calibrations when applicable. Additionally, the algorithm has been modified to improve detectability of sensors approaching end of life. Except the modified transmitter firmware, the sensor/applicator, transmitter hardware, and mobile app remain unchanged.

5.5 INDICATIONS FOR USE:

5.5.1 Dexcom G6 Continuous Glucose Monitoring (CGM) System

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.

5.5.2 Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) 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.

5.6 COMPARISON WITH THE PREDICATE DEVICE:

5.6.1 Dexcom G6 Continuous Glucose Monitoring (CGM) System

Device	**Dexcom G6 CGM System (K191450, Predicate)**	**Dexcom G6 CGM System (subject device)**
Trade Name	Dexcom G6 Continuous Glucose Monitoring (CGM) System	**Same**

Device	Dexcom G6 CGM System (K191450, Predicate)	Dexcom G6 CGM System (subject device)
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 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**

Device	Dexcom G6 CGM System (K191450, Predicate)	Dexcom G6 CGM System (subject device)
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. 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**
Glucose Value Estimation Algorithm	Joint Probability Algorithm (JPA)	**Substantially Equivalent** with no adverse impact on safety or effectiveness. JPA was optimized to improve data availability by better handling calibrations when applicable. The accuracy of the proposed G6 CGM System was demonstrated to meet the iCGM (21 CFR 862.1355) Special Controls requirements (**Section 20**, *Performance Testing - Clinical*). Dexcom conducted software verification and validation to ensure predefined requirements were met (**Section 16**, *Software Verification and Validation Testing*).

Device	Dexcom G6 CGM System (K191450, Predicate)	Dexcom G6 CGM System (subject device)
Algorithm Self-Diagnostics	Noise Management Progressive Sensor Decline (PSD) detection	**Substantially Equivalent** with no adverse impact on safety or effectiveness. Noise Management was modified to better handle noise events to improve data availability while retaining the accuracy. Additionally, progressive sensor decline detection was modified to improve detectability of sensors that are approaching end of life. The accuracy of the proposed G6 CGM System was demonstrated to meet the iCGM (21 CFR 862.1355) Special Controls requirements (**Section 20**, *Performance Testing - Clinical*). Software verification and validation demonstrated the proposed G6 firmware meets the predefined requirements (**Section 16**, *Software Verification and Validation Testing*).
Factory Calibration	Yes	**Same**
Optional Calibration	Yes	**Same**
Features	Connect to Dexcom Share: Users can share their glucose data with followers.	**Same**
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**

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

Device	Dexcom G6 Glucose Program System (K191450, Predicate)	Dexcom G6 Glucose Program System (subject device)
Trade Name	Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) System	**Same**

Device	Dexcom G6 Glucose Program System (K191450, Predicate)	Dexcom G6 Glucose Program System (subject device)
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. 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	**Same**

Device	Dexcom G6 Glucose Program System (K191450, Predicate)	Dexcom G6 Glucose Program System (subject device)
	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. 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 six, or twelve hours of glucose data on a graph with high/low glucose thresholds. 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**
Glucose Value Estimation Algorithm	Joint Probability Algorithm	**Substantially Equivalent** with no adverse impact on safety or effectiveness. JPA was optimized to improve data availability by better handling calibrations when applicable. The accuracy of the proposed G6 CGM System was demonstrated to meet the iCGM (21 CFR 862.1355) Special Controls requirements (**Section 20**, *Performance Testing - Clinical*). Dexcom conducted software verification and validation to ensure predefined requirements were met (**Section 16**, *Software Verification and Validation Testing*).

Device	Dexcom G6 Glucose Program System (K191450, Predicate)	Dexcom G6 Glucose Program System (subject device)
Algorithm Self-Diagnostics	Noise Management Progressive Sensor Decline (PSD) detection	**Substantially Equivalent** with no adverse impact on safety or effectiveness. Noise Management was modified to better handle noise events to improve data availability while retaining the accuracy. Additionally, progressive sensor decline was modified to improve detectability of sensors which are approaching end of life. The accuracy of the proposed G6 CGM System was demonstrated to meet the iCGM (21 CFR 862.1355) Special Controls requirements (**Section 20**, *Performance Testing - Clinical*). Software verification and validation demonstrated the proposed G6 firmware meets the predefined requirements (**Section 16**, *Software Verification and Validation Testing*).
Factory Calibration	Yes	**Same**
Optional Calibration	Yes	**Same**
Features	Connect to Dexcom Share: Users can share their glucose data with followers. 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. 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 and Dexcom G6 Glucose Program CGM System with modified algorithm are 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 and Dexcom G6 Glucose Program CGM System with modified algorithm share the same technological characteristics as the predicate device (K191450).

5.8 SUMMARY OF PERFORMANCE TESTING

The proposed Dexcom G6 CGM System and Dexcom G6 Glucose Program CGM System were verified and validated according to Dexcom's internal design control process and in accordance with special controls for integrated continuous glucose monitoring systems. This testing demonstrated that the proposed systems performed according to their respective specifications, and the proposed systems have met their respective technological and performance criteria, which have not changed from the predicate device (K191450).

5.9 CONCLUSIONS

The information provided in this premarket notification support that the proposed Dexcom G6 CGM System and Dexcom G6 Glucose Program CGM System are substantially equivalent to their respective predicates 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.