January 29, 2020

Dexcom, Inc.
Linda Wang
Staff Regulatory Affairs Specialist
6340 Sequence Drive
San Diego, CA 92121

Re: K193642
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: December 27, 2019
Received: December 30, 2019

Dear Linda Wang:

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.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193642

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 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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1. 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: **K193642**

1.1 SUBMITTER

Sponsor	Dexcom 6340 Sequence Drive San Diego, CA 92121
Contact Person	Linda Wang Staff Regulatory Affairs Specialist Phone: (858) 203-6816 Fax: (858) 332-0204 Email: linda.wang@dexcom.com
Alternative Contact	Bryan Osborne Regulatory Affairs Specialist Phone: (858) 875-9896 Email: bosborne@dexcom.com
Date Prepared	December 27, 2019

1.2 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

1.3 PREDICATE DEVICE

Dexcom G6 Glucose Program Continuous Glucose Monitoring System (K192787, cleared October 25, 2019)

1.4 REFERENCE DEVICE

Dexcom G6 Glucose Program Continuous Glucose Monitoring System (K182041, cleared October 26, 2018)

1.5 DEVICE DESCRIPTION

The proposed Dexcom G6 Glucose Program Continuous Glucose Monitoring 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 either the Android app (part of the predicate system) or iOS app (part of the proposed system). The app displays the current glucose reading (updated every 5 minutes) and glucose trends from the transmitter. The app alert 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 the Follow mobile application.

1.6 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.

1.7 COMPARISON WITH THE PREDICATE DEVICE

Device	Predicate Device	Proposed 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	Same

Device	Predicate Device	Proposed Device
	purpose of managing a disease or condition related to glycemic control.	
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.	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
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
Features	**Connect to Dexcom Share:** Users can share their glucose data with up to three 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 user interface and user experience. Commonly understood navigation tools and features. Color-coded graphics.	Same
Transmitter	G6 Epoxy Transmitter and G6 Welded Transmitter	Same
Compatibility with intended environments	Compatible with Android OS version 7.0 and above	Same for Android **Compatible with iOS version 13.2 and above**

1.8 TECHNOLOGICAL 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 (K192787). The proposed Dexcom Glucose Program System adds an iOS-based app to the current/predicate CGM system's Android app capability.

1.9 SUMMARY OF PERFORMANCE TESTING

The proposed Dexcom Glucose Program System was verified and validated according to Dexcom's internal design control process. All testing performed on the predicate device and reference device 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 completed for the predicate device (K192787) remain applicable. Software testing was completed to ensure all requirements of the proposed iOS app are fulfilled.

1.10 CONCLUSION

The proposed Dexcom Glucose Program System is substantially equivalent to the predicate system as it shares the same intended use, indications for use, and technological characteristics. The difference between the proposed Dexcom Glucose Program System and the predicate device (cleared under K192787) is the addition of the iOS app, but the proposed app has the same functionality as the current Android app. Therefore, the proposed modification does not raise different questions of safety and effectiveness.