January 11, 2023

Dexcom, Inc.
Brittney Shaver
Senior Specialist, Regulatory Affairs
6340 Sequence Drive
San Diego, California 92121

Re: K223931
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: December 29, 2022
Received: December 30, 2022

Dear Brittney Shaver:

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 -S

Marianela Perez-Torres, Ph.D.
Acting Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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)*
K223931

Device Name
Dexcom G6 Continuous Glucose Monitoring (CGM) 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.

7. 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: K223931

7.1. Submitter

Dexcom, Inc.
6340 Sequence Dr.
San Diego, CA 92121
Contact: Brittney Shaver
Position/Title: Senior Specialist, Regulatory Affairs
Phone: 858-203-6381
Email: brittney.shaver@dexcom.com

Secondary Contact: Linda Wang
Position/Title: Manager, Regulatory Affairs
Phone: 858-203-6397
Email: linda.wang@dexcom.com

Date Prepared: January 4, 2023

7.2. 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

7.3. Predicate and Reference Devices

Predicate Device
Dexcom G6 Continuous Glucose Monitoring (CGM) System (K221259, cleared July 29, 2022)
Reference Devices
Dexcom G6 Continuous Glucose Monitoring (CGM) System (DEN170088, granted March 27, 2018)
Dexcom G7 Continuous Glucose Monitoring (CGM) System (K213919, cleared December 8, 2022)

7.4. Device Description

The proposed Dexcom G6 CGM System is based on the same physical principles and fundamental design as the predicate but includes an alternative receiver. This receiver has identical hardware to the G7 receiver (K213919). The Dexcom G6 CGM System is designed to

function as intended with either the proposed or current commercial receiver. The proposed receiver has the same function as the commercial receiver.

7.4.1. Dexcom G6 CGM System

The Dexcom G6 Continuous Glucose Monitoring System is an interoperable connected device that measures and displays glucose values for patients with diabetes. The G6 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 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 CGM System is designed to be used alone or in conjunction with digitally connected devices. The G6 CGM System can communicate Estimated Glucose Values (EGV) and other information wirelessly and securely to and from these digitally connected devices.

7.5. Indications for Use

7.5.1. Dexcom G6 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.

7.6. Comparison with the Predicate Device

7.6.1. Dexcom G6 CGM System

Device	Predicate Device (K221259)	Subject Device
Trade Name	Dexcom G6 Continuous Glucose Monitoring (CGM) System	Same
Manufacturer	Dexcom, Inc.	Same
General Device Characteristics		

Device	Predicate Device (K221259)	Subject Device
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
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	Same
Factory Calibration	Yes	Same
Optional Calibration	Yes	Same
Features	Connect to Dexcom Share: Users can share their glucose data with followers. Partner Web APIs: Users can share their glucose data with client software.	Same
Human Factors	System usability validated through human factors testing.	Same
Compatibility with Intended Environments	Android OS and Apple iOS	Same
Receiver	Touchscreen Receiver	Non-touchscreen receiver.

7.7. Technological Characteristics

The proposed Dexcom G6 CGM System is used to measure glucose values via amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction. The proposed Dexcom G6 CGM System shares the same technological characteristics as the predicate (K221259).

7.8. Summary of Performance Testing

The proposed Dexcom G6 CGM System was 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 system performs according to specifications and meets the technological and performance criteria which have not changed from the predicate device. The proposed system uses the same sensor, applicator, transmitter, and app requirements and design specifications as the predicate device. Therefore, performance testing and software verification and validation testing completed for the predicate device (K221259) remain applicable. Firmware and hardware testing was completed to ensure all requirements of the proposed receiver are fulfilled. This testing demonstrated that the proposed system performs according to specifications and meets the technological and performance criteria which have not changed from the predicate device.

7.9. Conclusions

The proposed Dexcom G6 CGM System is substantially equivalent to the predicate system as it is identical with regards to intended use and indications for use; and there are no differences in technological characteristics that raise different questions of safety and effectiveness.