December 7, 2022

Dexcom, Inc.
Holly Drake
Director, Regulatory Affairs
6340 Sequence Dr.
San Diego, California 92121

Re: K213919
Trade/Device Name: Dexcom G7 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: September 14, 2022
Received: September 15, 2022

Dear Holly Drake:

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)*
K213919

Device Name
Dexcom G7 Continuous Glucose Monitoring (CGM) System

Indications for Use *(Describe)*
The Dexcom G7 Continuous Glucose Monitoring (CGM) System is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons 2 years and older.

The Dexcom G7 CGM System is intended to replace fingerstick BG testing for diabetes treatment decisions. Interpretation of the Dexcom G7 CGM System results should be based on the glucose trends and several sequential sensor readings over time. The Dexcom G7 CGM System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.

The Dexcom G7 CGM System is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. The Dexcom G7 CGM System can be used alone or in conjunction with these digitally connected medical devices for the purposes 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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5 510(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: K213919

5.1 SUBMITTER:

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

Primary Contact: Holly Drake
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Date Prepared: November 29, 2022

5.2 DEVICE NAMES AND CLASSIFICATION:

Proprietary Name	Dexcom G7 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 (K201328)

5.4 DEVICE DESCRIPTION:

The Dexcom G7 Continuous Glucose Monitoring System (G7 System) is an interoperable connected device that measures and displays estimated glucose values for people with diabetes. The G7 System consists of the following components: the Glucose Sensing Subsystem (GSS), the Mobile Application Subsystem (MAS), the Receiver Subsystem (RVS). The GSS is comprised of the sensor applicator and on-body wearable, which includes a Bluetooth Low Energy (BLE) molded transmitter, adhesive patch and sensor. 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 period of up to 10 days with an extended 12-hour grace period after the sensor session. The grace period allows additional time for the user to change the sensor at a convenient time.

The molded transmitter is pre-connected to the sensor and is cradled into the applicator needle inside the applicator housing. The applicator external housing consists of a cap and shroud which utilize a threaded cap and seal to create the sterile barrier system. A deployment lock mechanism prevents insertion of the on-body wearable until the applicator is pressed against the insertion site. The insertion is a single button press vertical spring deployed mechanism which introduces the sensor via the needle into the subcutaneous tissue, while also placing the embedded wearable onto the body which adheres to the skin via an adhesive patch.

After deployment, the molded transmitter initiates automatic wakeup and session start. The sensor's small and flexible wire converts glucose to electrical current and the transmitter samples the electrical current produced by the sensor. The transmitter's onboard algorithm converts these measurements into estimated glucose values and calculates the glucose rate of change which are sent every 5 minutes to the MAS and/or the RVS. The MAS and RVS are display devices which present the current glucose reading and glucose trend to the user. Both display devices alert the user when glucose levels are outside of a target zone and when specific system states occur. The G7 System is designed to communicate to one or both display devices simultaneously.

The G7 System is also designed to communicate estimated glucose values, trend and system information to other compatible electronic interfaces via the following secure wireless connections:

- 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.

- Dexcom Partner Web APIs: The Dexcom Partner Web APIs enable secure and reliable communication of CGM data to authorized client software intended to receive the data through the cloud. The Partner Web APIs is not intended to be used by automated insulin delivery systems (AID).

The proposed G7 CGM System is based on the same mode of operation and mechanism of reaction as the predicate G6 CGM System (K201328), which uses a wire-type sensing mechanism that continuously measures interstitial fluid glucose levels and a BLE enabled radio transmitter to wirelessly communicate CGM data to compatible display devices at regular 5-minute intervals. These data are also able to be reliably and securely transmitted to other digitally connected devices, including automated insulin dosing systems, for the purpose of managing diabetes. The Dexcom Partner Web APIs also enable secure and reliable communication of CGM data to authorized client software as another compatible electronic interface.

The G7 CGM System primarily improves upon the user experience of the predicate G6 CGM System by providing a fully enclosed miniaturized wearable with pre-connected sensor that is applied to the body in a single button press. The MAS and RVS include redesigned user interfaces which simplify the use of CGM while including retrospective summary reports for quick access by the user.

5.5 INDICATIONS FOR USE

The Dexcom G7 Continuous Glucose Monitoring System (Dexcom G7 CGM System or G7) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons 2 years and older.

The Dexcom G7 CGM System is intended to replace fingerstick BG testing for diabetes treatment decisions. Interpretation of the Dexcom G7 CGM System results should be based on the glucose trends and several sequential sensor readings over time. The Dexcom G7 CGM System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.

The Dexcom G7 CGM System is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. The Dexcom G7 CGM System can be used alone or in conjunction with these digitally connected medical devices for the purpose of managing diabetes.

5.6 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Device and Predicate Device	Subject Device (K213919)	Predicate Device (K201328)
Device Trade Name	Dexcom G7 Continuous Glucose Monitoring System	Dexcom G6 Continuous Glucose Monitoring System
Manufacturer	Dexcom, Inc.	**Same**
General Device Characteristics		
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 G7 Continuous Glucose Monitoring System (Dexcom G7 CGM System or G7) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons 2 years and older. The Dexcom G7 CGM System is intended to replace fingerstick BG testing for diabetes treatment decisions. Interpretation of the Dexcom	**Same except for Trade Name** 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.

Device and Predicate Device	Subject Device (K213919)	Predicate Device (K201328)
	G7 CGM System results should be based on the glucose trends and several sequential sensor readings over time. The Dexcom G7 CGM System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. The Dexcom G7 CGM System is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. The Dexcom G7 CGM System can be used alone or in conjunction with these digitally connected medical devices for the purpose of managing diabetes.	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.
Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction	**Same**
Sample Type	Interstitial fluid	**Same**
Enzyme	Glucose Oxidase	**Same**
Clinical Setting	Home use	**Same**
Intended Use Population	Persons with diabetes age 2 and above	**Same**
Measuring Range	40-400 mg/dL	**Same**
Interferent Substances	Hydroxyurea, Acetaminophen (e.g. > 1 gram every 6 hours in adults)	**Same**
Anatomical Wear Locations	Arm (age 2+ years); Upper buttocks (age 2-6 years)	Abdomen (age 2+ years); Upper buttocks (age 2-17 years)

Device and Predicate Device	Subject Device (K213919)	Predicate Device (K201328)
Data Displayed	Current glucose value, current glucose trend, graph with recent glucose history, user entered events	**Same**
Calibration	Factory calibrated, optional manual calibration	**Same**
Situations when fingerstick is required to confirm sensor reading (adjunctive use)	• User's symptoms do not match the glucose value displayed by the device • No glucose value or trend is displayed by the device	**Same**
Primary Display Device	Mobile app installed on compatible smart device or Receiver	**Same**
Compatibility with Intended Environments	iOS and Android	**Same**
Glucose Alerts	Urgent low, urgent low soon, low glucose, high glucose, falling rate, rising rate	**Same**
Sensor Warm Up Time	Within 30 minutes (27 minutes)	2 hours
Sensor Life	Up to 10 days with a 12-hour grace period	Up to 10 days
Sterilization	Ethylene Oxide (EO)	Electron Beam radiation
Transmitter Life	Single Use (10.5 days)	Reusable (90 days)
Wireless Communication protocol	Bluetooth Core Specification v4.2	Bluetooth Core Specification v4.0
Wireless Communication range	20 feet	**Same**
Glucose reading interval	Autonomously every 5 minutes	**Same**

5.7 SUMMARY OF PERFORMANCE TESTING

The Dexcom G7 CGM System was verified and validated according to Dexcom's internal design control processes and in accordance with special controls for integrated continuous glucose monitors. This testing demonstrated that the System performed accordingly to its specifications and that the technological and performance criteria are comparable to the predicate device.

5.8 CONCLUSIONS

The Dexcom G7 CGM System is submitted as a proposed Integrated Continuous Glucose Monitoring (iCGM) designed to assist management of diabetes mellitus in persons 2 years and older. Information in this premarket notification demonstrates the Dexcom G7 CGM System conforms to the requirements of 21 CFR 862.1355 (iCGM Special Controls) and all mitigation measures necessary for identified risks to health are successfully implemented.

The submitted information in this premarket notification supports the Dexcom G7 CGM System is substantially equivalent to the Dexcom G6 CGM System as they are identical with regard to intended use and there are no differences in indications, technological characteristics or performance that raise new questions of safety and effectiveness.