May 15, 2023

Dexcom, Inc.
Bob Shen
Sr. Regulatory Affairs Specialist
6340 Sequence Dr
San Diego, CA 92121

Re: K231081
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: April 14, 2023
Received: April 17, 2023

Dear Bob Shen:

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,

Paula V. Caposino
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Paula Caposino, Ph.D.
Acting Deputy Division 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)*
K231081

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.

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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: K231081

7.1. Submitter

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Date Prepared: May 15, 2023

7.2. 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 862.1335
Product Code	QBJ
Review Panel	Clinical Chemistry

7.3. Predicate Device

The modified device is substantially equivalent to Dexcom G7 Continuous Glucose Monitoring (CGM) System, K213919. The changes described here do not change the intended use or the fundamental scientific technology of the modified device.

7.4. 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) 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 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 then completed with 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. The wearable adheres to the skin via an adhesive patch.

After deployment, the 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; the data are sent every 5 minutes to the MAS and/or the RVS. The MAS and RVS are display devices that 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 uses the same mode of operation and mechanism of reaction as the predicate G7 CGM System (K213919). The proposed G7 CGM System uses an alternate GSS wearable adhesive.

7.5. 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.

7.6. Comparison of Technological Characteristics with the Predicate Device

Device and Predicate Device	Predicate Device (K213919)	Subject Device
Device Trade Name	Dexcom G7 Continuous Glucose Monitoring (CGM) System	**Same**
Manufacturer	Dexcom, Inc.	**Same**
General Device Characteristics		
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	**Same**

Device and Predicate Device	Predicate Device (K213919)	Subject Device
	these digitally connected medical devices for the purpose of managing diabetes.	
Clinical Application	Management of diabetes mellitus	**Same**
Clinical Setting	Home use	**Same**
Principle of Operation	Amperometric measurement of current proportional to glucose concentration in interstitial fluid via glucose oxidase chemical reaction	**Same**
Data Displayed	Current glucose value, current glucose trend, graph with recent glucose history, user entered events	**Same**
Calibration	Factory calibrated, optional manual calibration	**Same**
Anatomical Wear Locations	Arm (age 2+ years); Upper buttocks (age 2-6 years)	**Same**
Compatibility with Intended Environments	iOS and Android	**Same**
Adhesive Patch	Acrylic adhesive backed with non-woven polyester (NPET).	**Substantially equivalent** with no adverse impact on safety or effectiveness. The subject device uses an alternate adhesive patch with acrylic adhesive backed with non-woven polyurethane (PU).

7.7. Technological Characteristics

The proposed Dexcom G7 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 G7 CGM System shares the same technological characteristics as the predicate (K213919).

7.8. Summary of Performance Testing

The proposed Dexcom G7 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 performed according to its specifications; and the proposed system has met its technological and performance criteria which have not changed from the predicate device.

7.9. Conclusions

The proposed Dexcom G7 CGM System is substantially equivalent to the predicate as it is 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.