April 23, 2024

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

Re: K240902
Trade/Device Name: Dexcom G7 Continuous Glucose Monitoring System
Regulation Number: 21 CFR 862.1355
Regulation Name: Integrated Continuous Glucose Monitoring System
Regulatory Class: Class II
Product Code: QBJ
Dated: April 1, 2024
Received: April 2, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

Dexcom G7 Continuous Glucose Monitoring System

Indications for Use *(Describe)*

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.

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.

510(k) #:

510(k) Summary

Prepared on: 2024-04-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Dexcom Inc.
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Correspondent Contact	Mr. Bob Shen
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Dexcom G7 Continuous Glucose Monitoring System
Common Name	Integrated continuous glucose monitoring system
Classification Name	Integrated Continuous Glucose Monitoring System, Factory Calibrated
Regulation Number	862.1355
Product Code(s)	QBJ, KGX (CLASS 1) - TAPE AND BANDAGE, ADHESIVE

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K234133	Dexcom G7 Continuous Glucose Monitoring System	QBJ

Device Description Summary

21 CFR 807.92(a)(4)

The Dexcom G7 Continuous Glucose Monitoring System (G7 System) is an interoperable continuous glucose monitoring (CGM) system intended to continuously measure the glucose in the interstitial fluid, calculate the glucose reading and make this available to the user. The G7 System is intended for single patient use at home and requires a prescription.

The G7 System comprises the following primary components: a wearable, consisting of a G7 sensor and transmitter worn on the body and a display device, which can be a G7 Mobile Application (Mobile App) on an iOS or Android OS smart device, or a G7 Receiver (Receiver).

To achieve the intended functions and performance of the G7 System, one sensor and at least one display device (App or Receiver) must be used together. The user must pair the display device(s) with each unique sensor to enable communication and start a sensor session. During an active session, the sensor reports new glucose data to the display device every 5-minutes. The display device then displays

glucose data and provides alerts and information signals to the user. The reportable glucose range for the G7 System is 40 mg/dL to 400 mg/dL. Glucose values below this range are reported as 'LOW' and glucose values above this range are reported as 'HIGH'. 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 G7 is an interoperable connected device that can communicate glucose readings and other information wirelessly and securely to and from 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 Mobile App communicates to another app on a single mobile platform
• The Mobile App communicates through the cloud to another software device
o 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).

Principle of Operation:
The principles of operation for the Dexcom G7 System remain the same as prior generations of Dexcom CGM Systems. The System uses a wire-type sensing mechanism that continuously measures interstitial glucose levels and uses a radio transmitter to wirelessly communicate glucose data to the display device for the user to see and use accordingly.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has the same technological characteristics as the predicate device. The difference between the subject device and predicate device is the BLE communication range specification and associated labeling updates. No design change was required to support the extended BLE communication range specification. The specification and labeling differences between the subject device and the predicate device do not constitute a new intended use. The subject device is as safe and effective as the predicate device and does not raise different questions of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The subject device G7 CGM System is substantially equivalent to the predicate device G7 CGM System. The difference between the subject device and predicate device is the BLE communication range specification and associated labeling updates. No design change was required to support the extended BLE communication range specification. The following performance characteristic was established through nonclinical testing performed on the subject device G7 CGM System:

- Communication Range testing: This testing demonstrates that the subject device G7 CGM System met the extended BLE communication range specification.

Nonclinical testing results demonstrate that the proposed G7 Continuous Glucose Monitoring System meets pre-defined acceptance criteria, support that the device is acceptable for its intended use, and is as safe and effective as the predicate device.

No clinical data was necessary to determine substantial equivalence.