December 17, 2025

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

Re: K253710
Trade/Device Name: Dexcom G7 Continuous Glucose Monitoring (CGM) System
Dexcom G7 15 Day 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: November 23, 2025
Received: November 24, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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.

510(k) Number *(if known)*
K253710

Device Name
Dexcom G7 15 Day Continuous Glucose Monitoring (CGM) System

Indications for Use *(Describe)*
The Dexcom G7 15 Day Continuous Glucose Monitoring (CGM) System (Dexcom G7 15 Day System or G7 15 Day) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons 18 years and older.

The Dexcom G7 15 Day CGM System is intended to replace fingerstick BG testing for diabetes treatment decisions. Interpretation of the Dexcom G7 15 Day CGM System results should be based on the glucose trends and several sequential sensor readings over time. The Dexcom G7 15 Day CGM System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.

The Dexcom G7 15 Day CGM System is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. The Dexcom G7 15 Day 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.

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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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.

510(k) Number *(if known)*
K253710

Device Name
Dexcom G7 Continuous Glucose Monitoring (CGM) 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.

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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: K253710
Prepared on: 2025-11-23

CONTACT DETAILS

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DEVICE NAME AND CLASSIFICATION

Device Trade Name	Dexcom G7 Continuous Glucose Monitoring (CGM) System Dexcom G7 15 Day Continuous Glucose Monitoring (CGM) 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

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LEGALLY MARKETED PREDICATE DEVICES

Predicate #	K240902
Predicate Trade Name	Dexcom G7 Continuous Glucose Monitoring System
Product Code	QBJ

Predicate #	K243214
Predicate Trade Name	Dexcom G7 15 Day Continuous Glucose Monitoring (CGM) System
Product Code	QBJ

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DEVICE DESCRIPTION SUMMARY

The Dexcom G7 Continuous Glucose Monitoring System (Dexcom G7 System) and the Dexcom G7 15 Day Continuous Glucose Monitoring System (Dexcom G7 15 Day System) are interoperable continuous glucose monitoring (CGM) systems intended to continuously measure the glucose in the interstitial fluid, calculate the glucose reading and make this available to the user. Both the Dexcom G7 System and the Dexcom G7 15 Day System are intended for single patient use at home and require a prescription.

The Dexcom G7 System and the Dexcom G7 15 Day System consist of the following primary components: a wearable, consisting of a 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 both the Dexcom G7 System and the Dexcom G7 15 Day 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 both the Dexcom G7 System and the Dexcom G7 15 Day 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 Dexcom G7 System sensor has an expected wear period of up to 10 days with an extended 12-hour grace period after the sensor session. The Dexcom G7 15 Day System sensor has an expected wear period of up to 15 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.

Both the Dexcom G7 System and the Dexcom G7 15 Day System are interoperable connected devices 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
    - 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).

<u>Principle of Operation</u>:
The principles of operation for the Dexcom G7 System and Dexcom G7 15 Day 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

Dexcom G7 Continuous Glucose Monitoring (CGM) System:
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.

Dexcom G7 15 Day Continuous Glucose Monitoring (CGM) System:
The Dexcom G7 15 Day Continuous Glucose Monitoring (CGM) System (Dexcom G7 15 Day CGM System or G7 15 Day) is a real time, continuous glucose monitoring device indicated for the management of diabetes in persons 18 years and older.

The Dexcom G7 15 Day CGM System is intended to replace fingerstick BG testing for diabetes treatment decisions. Interpretation of the Dexcom G7 15 Day CGM System results should be based on the glucose trends and several sequential sensor readings over time. The Dexcom G7 15 Day CGM System also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.

The Dexcom G7 15 Day CGM System is also intended to autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems. The Dexcom G7 15 Day 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

The indications for use are the same for the subject devices (Dexcom G7 CGM System and Dexcom G7 15 Day CGM System) and their respective predicate devices (K240902 and K243214).

TECHNOLOGICAL COMPARISON

The subject devices (Dexcom G7 CGM System and Dexcom G7 15 Day CGM System) have the same fundamental technological characteristics as their respective predicate devices (K240902 and K243214). The subject devices introduce an alternate transmitter on the wearable. Design differences between the subject devices and the predicate devices do not constitute a new intended use. The subject devices are as safe and effective as the predicate devices and do not raise different questions of safety and effectiveness.

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NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY AND CONCLUSIONS

The following performance characteristics were verified or validated through studies conducted on the subject devices, Dexcom G7 CGM System and Dexcom G7 15 Day CGM System:

- Electromagnetic Compatibility (EMC) Test:
  Dexcom conducted EMC tests in accordance with FDA-recognized consensus standards, including IEC 60601-1-2, RTCA DO-160G, and IEC 60601-4-2.

- Wireless Coexistence Test:
  Dexcom conducted Wireless Coexistence test in accordance with FDA-recognized consensus standards, including IEEE ANSI USEMCSC C63.27, and AAMI TIR69.

- Common Electromagnetic (EM) Emitters Tests:
  Dexcom conducted electromagnetic immunity tests against common EM emitters, including radio-frequency identification (RFID) readers, security and logistical systems, and household radio-frequency interference, and ensured that all established specifications were met.

- Electrical, Mechanical, and Thermal (EMT) Safety:
  Dexcom demonstrated compliance with the FDA-recognized consensus standards on electrical safety, including IEC 60601-1 and all applicable collateral standards.

- Hardware Design Verification:
  Hardware verification testing, including static sensitivity test, potentiostat leakage current test, communication range and reliability test (receiver), communication range test (smart device), TMR (tunnel magneto-resistance) deployment test, and battery life accelerated aging test, were conducted to confirm that the hardware used in the Dexcom G7 CGM System and Dexcom G7 15 Day CGM System performed in accordance with established specifications.

- Software Verification and Validation:
  Software verification and validation testing was conducted to confirm that the software used in the Dexcom G7 CGM System and Dexcom G7 15 Day CGM System performed in accordance with established specifications, IEC 62304 and FDA Guidance document “Guidance for the Content of Premarket Submissions for Device Software Functions,” June 14, 2023. Evaluation activities included code review, unit, software verification, system integration, and system level testing which verified functionality of the device against established software requirements. The system level testing included testing of data transmission reliability.

- Cybersecurity:
  Dexcom provided cybersecurity risk management summaries for the Dexcom G7 CGM System and Dexcom G7 15 Day CGM System that included analysis of confidentiality, integrity, and availability for data, information and software related to the G7 15 Day in accordance with the FDA Guidance “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions” (September 27, 2023). For each identified threat and vulnerability risk event scenario, risk assessment of impact to confidentiality, integrity, and availability was performed and documented within the cybersecurity risk management documentation. Appropriate risk mitigation

controls have been implemented and tested. In addition, Dexcom has controls and processes in place to ensure continued support for keeping the device secure and to ensure that the device firmware, software and components are malware free. Additional controls are also in place in manufacturing through distribution to ensure that the medical device firmware and software are malware free from point of origin to the hands of the end user.

Nonclinical testing results demonstrate that the Dexcom G7 CGM System and Dexcom G7 15 Day CGM System meet pre-defined acceptance criteria and support that the devices are acceptable for their intended use. The nonclinical data of the Dexcom G7 CGM System and Dexcom G7 15 Day CGM System support a substantial equivalence decision.