

K243214 Dexcom G7 15 Day Continuous Glucose Monitoring System

Apr 9, 2025
188 days to decisionK243214 · Product code: **QBJ** · Chemistry
Source: <https://www.510kdatabase.net/k243214/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Integrated Continuous Glucose Monitoring System, Factory Calibrated (QBJ)
Date received	Oct 3, 2024
Decision date	Apr 9, 2025
Days to decision	188 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dexcom, Inc.
Location	San Diego, CA, US
Contact	Holly Drake
Website	https://www.dexcom.com
510(k) history	24 submissions · 21 cleared · 2014-2026

Dexcom, Inc. is a medical device company headquartered in San Diego, US. The company specializes in continuous glucose monitoring systems and related chemistry devices. Dexcom has received FDA 510(k) clearances from total submissions since its first clearance in 2014. The company's regulatory portfolio is dominated by chemistry devices, which account for 92% of submissions. The latest clearance was granted in 2026, reflecting active ongoing development and regulatory engagement. The company's cleared device portfolio centers on continuous glucose monitoring technology. Re...

CLINICAL EVIDENCE - NCT05263258

[Trial of device that is not approved or cleared by the U.S. FDA]

Status	Withheld - <i>No results published to ClinicalTrials.gov</i>
Sponsor	[Redacted]

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05263258510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243214/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine). 510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026