

# K231081 Dexcom G7 Continuous Glucose Monitoring (CGM) System

May 15, 2023  
28 days to decisionK231081 · Product code: **QBJ** · Chemistry  
Source: <https://www.510kdatabase.net/k231081/>

## SUBMISSION DETAILS

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Integrated Continuous Glucose Monitoring System, Factory Calibrated (QBJ)
Date received	Apr 17, 2023
Decision date	May 15, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

---

Company	<b>Dexcom, Inc.</b>
Location	San Diego, CA, US
Contact	Bob Shen
Website	<a href="https://www.dexcom.com">https://www.dexcom.com</a>
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...