

# K223931 Dexcom G6 Continuous Glucose Monitoring (CGM) System

Jan 11, 2023  
12 days to decisionK223931 · Product code: **QBJ** · Chemistry  
Source: <https://www.510kdatabase.net/k223931/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Integrated Continuous Glucose Monitoring System, Factory Calibrated (QBJ)
Date received	Dec 30, 2022
Decision date	Jan 11, 2023
Days to decision	12 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Dexcom, Inc.</b>
Location	San Diego, CA, US
Contact	Brittney Shaver
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...