

## K203089 Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) System

Aug 17, 2021  
308 days to decisionK203089 · Product code: QDK · Chemistry  
Source: <https://www.510kdatabase.net/k203089/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Integrated Continuous Glucose Monitoring System For Non-intensive Diabetes Management (QDK)
Date received	Oct 13, 2020
Decision date	Aug 17, 2021
Days to decision	308 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	Bryan Osborne
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...