

# K192787 Dexcom G6 Glucose Program Continuous Glucose Monitoring (GCM) System

Oct 25, 2019  
25 days to decisionK192787 · Product code: QDK · Chemistry  
Source: <https://www.510kdatabase.net/k192787/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Integrated Continuous Glucose Monitoring System For Non-intensive Diabetes Management (QDK)
Date received	Sep 30, 2019
Decision date	Oct 25, 2019
Days to decision	25 days
Third-party review	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...

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