

**K252818 Dexcom Smart Basal**Nov 18, 2025  
75 days to decisionK252818 · Product code: **QRX** · Chemistry  
Source: <https://www.510kdatabase.net/k252818/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Glucose Monitor Informed Insulin Dose Calculator (QRX)
Date received	Sep 4, 2025
Decision date	Nov 18, 2025
Days to decision	75 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	Neeta Sharma
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...