

**K223537 FreeStyle Libre 2 System, FreeStyle Libre 3 System**Feb 21, 2023  
90 days to decisionK223537 · Product code: **QLG** · Chemistry  
Source: <https://www.510kdatabase.net/k223537/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Integrated Continuous Glucose Monitoring System, Factory Calibrated, Not For Use With Automated Insulin Delivery Systems (QLG)
Date received	Nov 23, 2022
Decision date	Feb 21, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Abbott Diabetes Care, Inc.</b>
Location	Alameda, CA, US
Contact	Simon Yuan
510(k) history	37 submissions · 37 cleared · 2000-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223537/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026