

**K193371 FreeStyle Libre 2 Flash Glucose Monitoring System**Jun 12, 2020  
190 days to decisionK193371 · Product code: **QLG** · Chemistry  
Source: <https://www.510kdatabase.net/k193371/>**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	Dec 5, 2019
Decision date	Jun 12, 2020
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Abbott Diabetes Care, Inc.</b>
Location	Alameda, CA, US
Contact	Naveen Thuramalla
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/k193371/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026