

**K210943 FreeStyle Libre 2 Flash Glucose Monitoring System
(with FreeStyle Libre 2 App)**Nov 22, 2021
237 days to decisionK210943 · Product code: **QLG** · Chemistry
Source: <https://www.510kdatabase.net/k210943/>**SUBMISSION DETAILS**

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	Mar 30, 2021
Decision date	Nov 22, 2021
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Diabetes Care, Inc.
Location	Alameda, CA, US
Contact	Ono Bacani
510(k) history	37 submissions · 37 cleared · 2000-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210943/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026