

K223435 FreeStyle Libre 3 Continuous Glucose Monitoring System

Apr 13, 2023
150 days to decisionK223435 · Product code: **QBJ** · Chemistry
Source: <https://www.510kdatabase.net/k223435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Integrated Continuous Glucose Monitoring System, Factory Calibrated (QBJ)
Date received	Nov 14, 2022
Decision date	Apr 13, 2023
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	FreeStyle Libre 2 Flash Glucose Monitoring System

APPLICANT

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

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