

K233537 FreeStyle Libre 3 Continuous Glucose Monitoring System

Apr 23, 2024
172 days to decisionK233537 · Product code: **QBJ** · Chemistry
Source: <https://www.510kdatabase.net/k233537/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Integrated Continuous Glucose Monitoring System, Factory Calibrated (QBJ)
Date received	Nov 3, 2023
Decision date	Apr 23, 2024
Days to decision	172 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	Sapna Ghelani
510(k) history	37 submissions · 37 cleared · 2000-2024

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