

K222447 FreeStyle Libre 2 Flash Glucose Monitoring SystemMar 3, 2023
200 days to decisionK222447 · Product code: **QBJ** · Chemistry
Source: <https://www.510kdatabase.net/k222447/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Integrated Continuous Glucose Monitoring System, Factory Calibrated (QBJ)
Date received	Aug 15, 2022
Decision date	Mar 3, 2023
Days to decision	200 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Freestyle Libre 3 Continuous Glucose Monitoring System

APPLICANT

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

CLINICAL EVIDENCE - NCT05251116

Study of an Interstitial Fluid Glucose Sensor

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	332 patients (actual)
Study sites	5 sites
Condition studied	Diabete Mellitus
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Aug 15, 2022
Sponsor	Abbott Diabetes Care (Industry)

Primary outcome**System Performance**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05251116

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