

K213996 FreeStyle Libre 3 Continuous Glucose Monitoring System

May 26, 2022
157 days to decisionK213996 · Product code: **QLG** · Chemistry
Source: <https://www.510kdatabase.net/k213996/>

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	Dec 20, 2021
Decision date	May 26, 2022
Days to decision	157 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	Rodney Huang
510(k) history	37 submissions · 37 cleared · 2000-2024

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