

K252357 Glucose2Oct 24, 2025
87 days to decisionK252357 · Product code: **CFR** · Chemistry
Source: <https://www.510kdatabase.net/k252357/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Jul 29, 2025
Decision date	Oct 24, 2025
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Abbott Ireland
Location	Lisnamuck, IE
Contact	Cherie Lipowsky
510(k) history	2 submissions · 2 cleared · 2025-2025

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