

K210633 Amylase2May 26, 2022
449 days to decisionK210633 · Product code: **JFJ** · Chemistry
Source: <https://www.510kdatabase.net/k210633/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Mar 3, 2021
Decision date	May 26, 2022
Days to decision	449 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Ireland Diagnostics Division
Location	Longford, IE
Contact	Magdalena Suszko
510(k) history	8 submissions · 8 cleared · 2021-2023

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