

**K223317 Alkaline Phosphatase2**Jul 21, 2023  
266 days to decisionK223317 · Product code: **CJE** · Chemistry  
Source: <https://www.510kdatabase.net/k223317/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes (CJE)
Date received	Oct 28, 2022
Decision date	Jul 21, 2023
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Abbott Ireland Diagnostics Division</b>
Location	Longford, IE
Contact	Julian Braz
510(k) history	8 submissions · 8 cleared · 2021-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223317/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 24, 2026