

**K203597 Cholesterol2**Jun 30, 2022  
568 days to decisionK203597 · Product code: **CHH** · Chemistry  
Source: <https://www.510kdatabase.net/k203597/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Dec 9, 2020
Decision date	Jun 30, 2022
Days to decision	568 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	Tracy Schmidt
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/k203597/> 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 25, 2026