

**K042443 SPOTCHEM HDL, TOTAL CHOLESTEROL AND TRIGLYCERIDE REAGENT TESTS AND PANEL**

Nov 24, 2004  
76 days to decision

K042443 · Product code: **CHH** · Chemistry  
Source: <https://www.510kdatabase.net/k042443/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Sep 9, 2004
Decision date	Nov 24, 2004
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Arkray, Inc.</b>
Location	Beverly, MA, US
Contact	HELEN LANDICHO
510(k) history	18 submissions · 18 cleared · 2002-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k042443/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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