

**K113382 ACE ALT REAGENT**Jul 19, 2012  
246 days to decisionK113382 · Product code: **CKA** · Chemistry  
Source: <https://www.510kdatabase.net/k113382/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nadh Oxidation/nad Reduction, Alt/sgpt (CKA)
Date received	Nov 16, 2011
Decision date	Jul 19, 2012
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Alfa Wassermann</b>
Location	West Caldwell, NJ, US
Contact	HYMAN KATZ
510(k) history	4 submissions · 4 cleared · 2012-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113382/> 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 June 8, 2026