

**K131515 ACE -GT REAGENT**Aug 14, 2013  
78 days to decisionK131515 · Product code: **KLI** · Chemistry  
Source: <https://www.510kdatabase.net/k131515/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Non-radiolabeled, Total Thyroxine (KLI)
Date received	May 28, 2013
Decision date	Aug 14, 2013
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary
Other names	ACE LIPASE RAGENT; ACE T4 REAGENT

**APPLICANT**

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Company	<b>Alfa Wassermann</b>
Location	West Caldwell, NJ, US
Contact	HYMAN KATZ, PH.D.
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/k131515/>; 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