

**K113436 ACE ALKALINE PHOSPHATASE REAGENT, ACE
AMYLASE REAGENT, ACE LDH-L REAGENT**Jul 12, 2012
234 days to decisionK113436 · Product code: CJE · Chemistry
Source: <https://www.510kdatabase.net/k113436/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes (CJE)
Date received	Nov 21, 2011
Decision date	Jul 12, 2012
Days to decision	234 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113436/> Data sourced from FDA 510(k) public records (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. - Generated June 8, 2026