

K131351 ACE ALKALINE PHOSPHATASE REAGENT, AMYLASE REAGENT, ALT REAGENT, AST REAGENTAug 15, 2013
97 days to decisionK131351 · Product code: CJE · Chemistry
Source: <https://www.510kdatabase.net/k131351/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes (CJE)
Date received	May 10, 2013
Decision date	Aug 15, 2013
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alfa Wassermann Diagnostic Technologies, LLC
Location	West Caldwell, NJ, US
Contact	HYMAN KATZ
510(k) history	2 submissions · 2 cleared · 2013-2018

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