

K113435 ACE CARBON DIOXIDE(CO2-LC) REAGENT, ACE DIRECT BILIRUBIN REAGENT, ACE TOTAL BILIRUBIN REAGENT, ACE MAGNESIUM REAGENTJul 2, 2012
224 days to decisionK113435 · Product code: **KHS** · Chemistry
Source: <https://www.510kdatabase.net/k113435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic, Carbon-dioxide (KHS)
Date received	Nov 21, 2011
Decision date	Jul 2, 2012
Days to decision	224 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/k113435/>; 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