

K112538 ACE CHOLESTEROL REAGENT, ACE HDL-C REAGENT, ACE LDL-C REAGENT, ACE TRIGLYCERIDES REAGENTMar 29, 2012
210 days to decisionK112538 · Product code: **CHH** · Chemistry
Source: <https://www.510kdatabase.net/k112538/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Sep 1, 2011
Decision date	Mar 29, 2012
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alfa Wassermann Diagnostic Technologies, Inc.
Location	West Caldwell, NJ, US
Contact	HYMAN KATZ
510(k) history	21 submissions · 21 cleared · 2008-2013

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