

**K123018 ACE ALERA CLINICAL CHEMISTRY SYSTEM, ACE  
GLUCOSE REAGENT, ACE ION SELECTIVE ELECTRODE (ISE)  
MODULE**Apr 23, 2013  
207 days to decisionK123018 · Product code: **CFR** · Chemistry  
Source: <https://www.510kdatabase.net/k123018/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	Sep 28, 2012
Decision date	Apr 23, 2013
Days to decision	207 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123018/> 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