

**K113389 ACE CK REAGENT,ACE BUN/UREA REAGENT,ACE URIC ACID REAGENT,ACE CREATININE REAGENT**

Aug 10, 2012  
268 days to decision

K113389 · Product code: **CDN** · Chemistry  
Source: <https://www.510kdatabase.net/k113389/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease, Photometric, Urea Nitrogen (CDN)
Date received	Nov 16, 2011
Decision date	Aug 10, 2012
Days to decision	268 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
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/k113389/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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