

K103615 ACE UREA NITROGEN REAGENT, CALCIUM-ARSEAZO REAGENT, CREATININE REAGENT, INORGANIC PHOSPHORUS U.V. REAGENT, URINE STANDARDSep 8, 2011
273 days to decisionK103615 · Product code: **CDN** · Chemistry
Source: <https://www.510kdatabase.net/k103615/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease, Photometric, Urea Nitrogen (CDN)
Date received	Dec 9, 2010
Decision date	Sep 8, 2011
Days to decision	273 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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