

K131488 ACE ALBUMIN REAGENT, ACE TOTAL PROTEIN REAGENT, ACE CALCIUM-ARSENazo REAGENT AND ACE PHOSPHORUS REAGENTAug 19, 2013
88 days to decisionK131488 · Product code: **CIX** · Chemistry
Source: <https://www.510kdatabase.net/k131488/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bromocresol Green Dye-binding, Albumin (CIX)
Date received	May 23, 2013
Decision date	Aug 19, 2013
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alfa Wassermann Diagnostics Technologies, LLC
Location	West Caldwell, NJ, US
Contact	HYMAN KATZ
510(k) history	3 submissions · 3 cleared · 2012-2013

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