FDA 510(k) Premarket Notification

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

CLEARED

Aug 10, 2012
268 days to decision

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

SUBMISSION DETAILS

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

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