

K152590 ACCU NEWS Drug Screening Test Card/Urine CupApr 15, 2016
218 days to decisionK152590 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k152590/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Sep 10, 2015
Decision date	Apr 15, 2016
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Coretests, Inc.
Location	Carlsbad, CA, US
Contact	ERIC SUN
510(k) history	2 submissions · 2 cleared · 2015-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152590/> Data sourced from FDA 510(k) public records (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. - Generated June 3, 2026