FDA 510(k) Premarket Notification

K122809 Advin Multi-Drug Screen Test Cassette, Dip Card and Cup

CLEARED

Jun 17, 2013
277 days to decision

K122809 · Product code: **DKZ** · Toxicology
Source: https://www.510kdatabase.net/k122809/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Sep 13, 2012
Decision date	Jun 17, 2013
Days to decision	277 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Advin Biotech**
Location	San Diego, CA, US
Contact	EDWARD TUNG
510(k) history	1 submissions · 1 cleared · 2013-2013

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k122809/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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