FDA 510(k) Premarket Notification

CLEARED

K143500 Immunalysis Amphetamine Urine Enzyme Immunoassay, Immunalysis Amphetamine Urine Calibrator, Immunalysis Amphetamine Urine Control Set

Feb 6, 2015
58 days to decision

K143500 · Product code: **DKZ** · Toxicology
Source: https://www.510kdatabase.net/k143500/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Dec 10, 2014
Decision date	Feb 6, 2015
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Immunalysis Corporation**
Location	Mchenry, IL, US
Contact	Joseph Ginete
510(k) history	50 submissions · 50 cleared · 1978-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k143500/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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