

**K153693 Immunalysis Methamphetamine Urine Enzyme
Immunoassay, Immunalysis Multi-Drug Calibrators**Mar 18, 2016
86 days to decisionK153693 · Product code: **LAF** · Toxicology
Source: <https://www.510kdatabase.net/k153693/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gas Chromatography, Methamphetamine (LAF)
Date received	Dec 23, 2015
Decision date	Mar 18, 2016
Days to decision	86 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

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