

K143502 Immunalysis Opiates Urine Enzyme Immunoassay, Immunalysis Opiates Urine Calibrators 300, Immunalysis Opiates Urine Calibrators 2000, Immunalysis Multi-Drug ControlsMay 20, 2015
161 days to decisionK143502 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k143502/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Dec 10, 2014
Decision date	May 20, 2015
Days to decision	161 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.netDevice record: <https://www.510kdatabase.net/k143502/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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