

**K141803 IMMUNALYSIS TRAMADOL URINE ENZYME
IMMUNOASSAY**Feb 12, 2015
224 days to decisionK141803 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k141803/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Jul 3, 2014
Decision date	Feb 12, 2015
Days to decision	224 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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