

**K131168 IMMUNALYSIS OXYCODONE ENZYME
IMMUNOASSAY**Jan 17, 2014
268 days to decisionK131168 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k131168/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Apr 24, 2013
Decision date	Jan 17, 2014
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Immunoanalysis 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/k131168/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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