

**K150275 Immunoassay, Immunoassay, Immunoassay 6-Acetylmorphine Urine Enzyme Immunoassay, Immunoassay 6-Acetylmorphine Urine Calibrator, Immunoassay 6-Acetylmorphine Urine Controls**Mar 9, 2015  
33 days to decisionK150275 · Product code: **DJG** · Toxicology  
Source: <https://www.510kdatabase.net/k150275/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Feb 4, 2015
Decision date	Mar 9, 2015
Days to decision	33 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Immunoassay Corporation</b>
Location	Mchenry, IL, US
Contact	Joseph Ginete
510(k) history	50 submissions · 50 cleared · 1978-2025

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