

**K141406 IMMUNALYSIS BUPRENORPHINE URINE ENZYME
IMMUNOASSAY, IMMUNALYSIS BUPRENORPHINE URINE
CONTROLS AND CALIBRATORS**Jul 1, 2014
34 days to decisionK141406 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k141406/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	May 28, 2014
Decision date	Jul 1, 2014
Days to decision	34 days
Third-party review	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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