

**K161216 Immunalysis SEFRIA Fentanyl Urine Enzyme
Immunoassay, Immunalysis Fentanyl Urine Calibrators**Jun 14, 2017
411 days to decisionK161216 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k161216/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Apr 29, 2016
Decision date	Jun 14, 2017
Days to decision	411 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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