

**K151771 Immunalysis Benzodiazepines Urine Enzyme
Immunoassay, Immunalysis Multi-Drug Calibrators**Jan 5, 2016
189 days to decisionK151771 · Product code: **JXM** · Toxicology
Source: <https://www.510kdatabase.net/k151771/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Benzodiazepine (JXM)
Date received	Jun 30, 2015
Decision date	Jan 5, 2016
Days to decision	189 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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