

**K161714 Immunalysis Barbiturates Urine Enzyme  
Immunoassay, Immunalysis Multi-Drug Calibrators**Oct 14, 2016  
115 days to decisionK161714 · Product code: **DIS** · Toxicology  
Source: <https://www.510kdatabase.net/k161714/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Barbiturate (DIS)
Date received	Jun 21, 2016
Decision date	Oct 14, 2016
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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