

**K051626 IMMUNALYSIS OPIATES ELISA FOR ORAL FLUIDS**Oct 13, 2005  
115 days to decisionK051626 · Product code: **DJG** · Toxicology  
Source: <https://www.510kdatabase.net/k051626/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Jun 20, 2005
Decision date	Oct 13, 2005
Days to decision	115 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k051626/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026