

**K103161 OMEGA LABORATORIES HAIR DRUG SCREENING  
ASSAY FOR OPIATES**Dec 13, 2011  
412 days to decisionK103161 · Product code: **DJG** · Toxicology  
Source: <https://www.510kdatabase.net/k103161/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Oct 27, 2010
Decision date	Dec 13, 2011
Days to decision	412 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Omega Laboratories, Inc.</b>
Location	South Lyon, MI, US
Contact	ROBERT J BARD, JD
510(k) history	9 submissions · 9 cleared · 2010-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103161/> 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 4, 2026