

**K131128 OMEGA LABORATORIES HAIR DRUG SCREENING  
ASSAY FOR COCAINE AND COCAINE METABOLITES**Nov 13, 2013  
204 days to decisionK131128 · Product code: **DIO** · Toxicology  
Source: <https://www.510kdatabase.net/k131128/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Apr 23, 2013
Decision date	Nov 13, 2013
Days to decision	204 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131128/> 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