

**K112808 OMEGA LABORATORIES HAIR DRUG SCREENING
ASSAY FOR COCAINE AND COCAINE METABOLITES**Jan 23, 2012
118 days to decisionK112808 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k112808/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Sep 27, 2011
Decision date	Jan 23, 2012
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112808/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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