

**K113139 LZI COCAINE METABOLITE HOMOGENEOUS ENZYME
IMMUNOASSAY,CALIBRATORS,CONTROLS**Nov 22, 2011
29 days to decisionK113139 · Product code: **DIO** · Chemistry
Source: <https://www.510kdatabase.net/k113139/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Oct 24, 2011
Decision date	Nov 22, 2011
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lin-Zhi International, Inc.
Location	San Jose, CA, US
Contact	BERNICE LIN
510(k) history	50 submissions · 49 cleared · 2002-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113139/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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