

**K050945 ORAL FLUID COCAINE METABOLITE  
HOMOGENEOUS ENZYME IMMUNOASSAYS, CALIBRATORS &  
CONTROLS**Mar 29, 2006  
349 days to decisionK050945 · Product code: **DIO** · Chemistry  
Source: <https://www.510kdatabase.net/k050945/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Apr 14, 2005
Decision date	Mar 29, 2006
Days to decision	349 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lin-Zhi International, Inc.</b>
Location	San Jose, CA, US
Contact	CHENG-I LIN
510(k) history	50 submissions · 49 cleared · 2002-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050945/>; 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