

**K131653 LZI ORAL FLUID AMPHETAMINE ENZYME
IMMUNOASSAY, CALIBRATORS, CONTROLS**Feb 4, 2014
244 days to decisionK131653 · Product code: **DKZ** · Toxicology
Source: <https://www.510kdatabase.net/k131653/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Jun 5, 2013
Decision date	Feb 4, 2014
Days to decision	244 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/k131653/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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