

**K141205 LZI ORAL FLUID 6-ACETYLMORPHINE ENZYME
IMMUNOASSAY, LZI ORAL FLUID 6-ACETYLMORPHINE
CALIBRATORS (5 ML), LZI ORAL FLUID 6**Feb 13, 2015
280 days to decisionK141205 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k141205/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	May 9, 2014
Decision date	Feb 13, 2015
Days to decision	280 days
Third-party review	No
Combination product	No
PCCP authorized	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

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