

**K101195 6-ACETYLMORPHINE ENZYME IMMUNOASSAY WITH
6-ACETYLMORPHINE CALIBRATORS AND CONTROLS**Jul 6, 2010
68 days to decisionK101195 · Product code: **DJG** · Chemistry
Source: <https://www.510kdatabase.net/k101195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Apr 29, 2010
Decision date	Jul 6, 2010
Days to decision	68 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/k101195/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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