FDA 510(k) Premarket Notification

K050733 OXYCODONE ENZYME IMMUNOASSAY AND OXYCODONE CALIBRATORS AND CONTROLS

CLEARED

Jun 13, 2005
88 days to decision

K050733 · Product code: **DJG** · Chemistry
Source: https://www.510kdatabase.net/k050733/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Mar 17, 2005
Decision date	Jun 13, 2005
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k050733/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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