FDA 510(k) Premarket Notification

K023795 PROPOXYPHENE ENZYME IMMUNOASSAY, CATALOG #0120 (500 TEST KIT), #0121 (5000 TEST KIT)

CLEARED

Jan 21, 2003
69 days to decision

K023795 · Product code: **JXN** · Toxicology
Source: https://www.510kdatabase.net/k023795/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Propoxyphene (JXN)
Date received	Nov 13, 2002
Decision date	Jan 21, 2003
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k023795/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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