FDA 510(k) Premarket Notification

K020368 OPIATE ENZYME IMMUNOASSAY, CATALOG # 0020 (500 TESTS KIT)

CLEARED

Jun 4, 2002
120 days to decision

K020368 · Product code: **DJG** · Toxicology
Source: https://www.510kdatabase.net/k020368/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Feb 4, 2002
Decision date	Jun 4, 2002
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary
Other names	CATALOG # 0021 (5000 TESTS KIT)

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/k020368/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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