

**K020763 COCAINE METABOLITE ENZYME IMMUNOASSAY
MODELS #0030 (500 TESTS KIT), #0031 (5000 TESTS KIT)**

May 10, 2002
64 days to decision

K020763 · Product code: **DIO** · Toxicology
Source: <https://www.510kdatabase.net/k020763/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Mar 7, 2002
Decision date	May 10, 2002
Days to decision	64 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/k020763/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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