

**K050988 OPIATE ORAL FLUID HOMOGENEOUS ENZYME
IMMUNOASSAY, CALIBRATORS AND CONTROLS**Apr 6, 2006
352 days to decisionK050988 · Product code: **DLG** · Toxicology
Source: <https://www.510kdatabase.net/k050988/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coating, Liquid, Glc (DLG)
Date received	Apr 19, 2005
Decision date	Apr 6, 2006
Days to decision	352 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050988/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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