

K051058 METHADONE ORAL FLUID HOMOGENEOUS ENZYME IMMUNOASSAY, CALIBRATORS AND CONTROLSMar 29, 2006
337 days to decisionK051058 · Product code: DJR · Toxicology
Source: <https://www.510kdatabase.net/k051058/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Methadone (DJR)
Date received	Apr 26, 2005
Decision date	Mar 29, 2006
Days to decision	337 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.netDevice record: <https://www.510kdatabase.net/k051058/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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