

K192433 LZI Methadone II Enzyme ImmunoassayOct 4, 2019
29 days to decisionK192433 · Product code: **DJR** · Toxicology
Source: <https://www.510kdatabase.net/k192433/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Methadone (DJR)
Date received	Sep 5, 2019
Decision date	Oct 4, 2019
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192433/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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