

K170416 LZI Methadone Metabolite Enzyme Immunoassay, LZI Methadone Metabolite (100 and 300) CalibratorsJun 26, 2017
136 days to decisionK170416 · Product code: DJR · Toxicology
Source: <https://www.510kdatabase.net/k170416/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Methadone (DJR)
Date received	Feb 10, 2017
Decision date	Jun 26, 2017
Days to decision	136 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

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