

**K031797 METHADONE METABOLITE (EDDP) ENZYME IMMUNOASSAY, CAT. NO. 190 (500 TEST KIT), NO. 191 (5000 TEST KIT)**Oct 10, 2003  
122 days to decisionK031797 · Product code: **DJR** · Toxicology  
Source: <https://www.510kdatabase.net/k031797/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Methadone (DJR)
Date received	Jun 10, 2003
Decision date	Oct 10, 2003
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lin-Zhi International, Inc.</b>
Location	San Jose, CA, US
Contact	CHENG-I LIN
510(k) history	50 submissions · 49 cleared · 2002-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031797/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026