

**K090844 BUPRENORPHINE ENZYME IMMUNOASSAY WITH  
NORBUPRENORPHINE CALIBRATORS AND CONTROLS**Jul 30, 2009  
125 days to decisionK090844 · Product code: **DJG** · Toxicology  
Source: <https://www.510kdatabase.net/k090844/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Mar 27, 2009
Decision date	Jul 30, 2009
Days to decision	125 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	MARIE 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/k090844/>; 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 June 22, 2026