

**K181159 LZI Fentanyl Enzyme Immunoassay**Dec 3, 2018  
216 days to decisionK181159 · Product code: **DJG** · Toxicology  
Source: <https://www.510kdatabase.net/k181159/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	May 1, 2018
Decision date	Dec 3, 2018
Days to decision	216 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lin-Zhi International, Inc.</b>
Location	San Jose, CA, US
Contact	Bernice 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/k181159/> 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