

K251634 LZI Fentanyl III Enzyme ImmunoassayJun 18, 2025
20 days to decisionK251634 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k251634/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	May 29, 2025
Decision date	Jun 18, 2025
Days to decision	20 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	Chris Wang
510(k) history	50 submissions · 49 cleared · 2002-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251634/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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