

K253082 LZI Buprenorphine II Enzyme ImmunoassayJan 16, 2026
115 days to decisionK253082 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k253082/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Sep 23, 2025
Decision date	Jan 16, 2026
Days to decision	115 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	Thet Wai
510(k) history	50 submissions · 49 cleared · 2002-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253082/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026