

K201223 LZI Tramadol Enzyme ImmunoassayJun 4, 2020
29 days to decisionK201223 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k201223/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	May 6, 2020
Decision date	Jun 4, 2020
Days to decision	29 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	Bernice Lin
510(k) history	50 submissions · 49 cleared · 2002-2026

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