

K192299 LZI Cotinine II Enzyme ImmunoassayNov 21, 2019
90 days to decisionK192299 · Product code: **MKU** · Toxicology
Source: <https://www.510kdatabase.net/k192299/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Nicotine And Nicotine Metabolites (MKU)
Date received	Aug 23, 2019
Decision date	Nov 21, 2019
Days to decision	90 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192299/> 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