

K201442 Lin-Zhi International, Inc. (LZI) Methamphetamine Enzyme Immunoassay for Pictus AnalyzersJul 31, 2020
60 days to decisionK201442 · Product code: LAF · Toxicology
Source: <https://www.510kdatabase.net/k201442/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gas Chromatography, Methamphetamine (LAF)
Date received	Jun 1, 2020
Decision date	Jul 31, 2020
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Diatron Group
Location	Westo, FL, US
Contact	Frank Matuszak
510(k) history	2 submissions · 2 cleared · 2011-2020

REGULATORY CONSULTANT

Consulting firm	Ammirati Regulatory Consulting
Contact	Erika Ammirati

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201442/> 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 June 4, 2026