

K240287 LYHER® Oral fluid Multi-Drug Test Kit (Cube)Mar 18, 2025
411 days to decisionK240287 · Product code: **DJC** · Toxicology
Source: <https://www.510kdatabase.net/k240287/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thin Layer Chromatography, Methamphetamine (DJC)
Date received	Feb 1, 2024
Decision date	Mar 18, 2025
Days to decision	411 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hangzhou Laihe Biotech Co., Ltd.
Location	Hangzhou, CN
Contact	Chen Yaohua
510(k) history	3 submissions · 3 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	Shanghai Thinkwell Consulting Co., Ltd.
Contact	Ethan Liu

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/k240287/> 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