

**K232604 LYHER® Urine Marijuana (THC) Test Kit (Strip),  
LYHER® Urine Marijuana (THC) Test Kit (Cassette)**Jan 10, 2024  
135 days to decisionK232604 · Product code: LDJ · Toxicology  
Source: <https://www.510kdatabase.net/k232604/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cannabinoids (LDJ)
Date received	Aug 28, 2023
Decision date	Jan 10, 2024
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Thinkwell Consulting Co., Ltd.</b>
Contact	Ethan Liu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232604/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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