FDA 510(k) Premarket Notification

CLEARED

K232597 LYHER® Urine Multi-Drug Test Kit(Cup), LYHER® Urine Multi-Drug Test Kit(Cassette), LYHER® Urine Multi-Drug Test Kit(Dipcard)

Jan 9, 2024
134 days to decision

K232597 · Product code: **DJG** · Toxicology
Source: https://www.510kdatabase.net/k232597/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Aug 28, 2023
Decision date	Jan 9, 2024
Days to decision	134 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	Yaohua Chen
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