

**K240654 SAFECARE Fentanyl Urine Test Cassette**Apr 10, 2024  
34 days to decisionK240654 · Product code: **NGL** · Toxicology  
Source: <https://www.510kdatabase.net/k240654/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Opiates, Over The Counter (NGL)
Date received	Mar 7, 2024
Decision date	Apr 10, 2024
Days to decision	34 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SAFECARE FYL Urine Test Cassette

**APPLICANT**

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Company	<b>Safecare Biotech (Hangzhou) Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Alex Qiu
510(k) history	9 submissions · 9 cleared · 2016-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>LSI International, Inc.</b>
Contact	Joe Shia

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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240654/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026