

K241741 SAFElife™ Fentanyl Urine Home Test (Cassette)Jul 16, 2024
29 days to decisionK241741 · Product code: **NGL** · Toxicology
Source: <https://www.510kdatabase.net/k241741/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Opiates, Over The Counter (NGL)
Date received	Jun 17, 2024
Decision date	Jul 16, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SAFElife™ Fentanyl (FTY) Urine Test Cassette; SAFElife™ T-Dip Fentanyl Urine Home Test (Dip Card); SAFElife™ T-Dip Fentanyl (FTY) Urine Test Panel

APPLICANT

Company	Guangzhou Wondfo Biotech Co., Ltd.
Location	Yardley, PA, US
Contact	Kaiyu Xiao
510(k) history	43 submissions · 43 cleared · 2005-2026

REGULATORY CONSULTANT

Consulting firm	LSI International, Inc.
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.netDevice record: <https://www.510kdatabase.net/k241741/> 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