

K240351 FaStep Fentanyl Rapid Test Device (Urine)Mar 6, 2024
30 days to decisionK240351 · Product code: **NGL** · Toxicology
Source: <https://www.510kdatabase.net/k240351/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Opiates, Over The Counter (NGL)
Date received	Feb 5, 2024
Decision date	Mar 6, 2024
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	FaStep Rapid Fentanyl Urine Test (Urine)

APPLICANT

Company	Assure Tech., LLC
Location	Wilmington, DE, US
Contact	Allen Chen
510(k) history	5 submissions · 5 cleared · 2024-2025

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/k240351/> 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