FDA 510(k) Premarket Notification

K240351 FaStep Fentanyl Rapid Test Device (Urine)

CLEARED

Mar 6, 2024
30 days to decision

K240351 · 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