

K240295 InstaStrip Fentanyl Rapid Test (Urine)Mar 28, 2024
56 days to decisionK240295 · Product code: **NGL** · Toxicology
Source: <https://www.510kdatabase.net/k240295/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Opiates, Over The Counter (NGL)
Date received	Feb 1, 2024
Decision date	Mar 28, 2024
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	InstaStrip Fentanyl Dipstick Test (Urine)

APPLICANT

Company	Instanosis, Inc.
Location	King Of Prussia, PA, US
Contact	Xiaofeng Xia
510(k) history	1 submissions · 1 cleared · 2024-2024

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)

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