FDA 510(k) Premarket Notification

CLEARED

K240949 Healgen® Accurate Fentanyl Rapid Test Cassette (Urine)

May 13, 2024
35 days to decision

K240949 · Product code: **NGL** · Toxicology
Source: https://www.510kdatabase.net/k240949/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Opiates, Over The Counter (NGL)
Date received	Apr 8, 2024
Decision date	May 13, 2024
Days to decision	35 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Healgen® Accurate Rapid Fentanyl Test Cassette (Urine); Healgen® Accurate Fentanyl Rapid Test Dip Card (Urine); Healgen® Accurate Rapid Fentanyl Test Dip Card (Urine); Healgen® Accurate Fentanyl Rapid Test Strip (Urine); Healgen® Accurate Rapid Fentanyl Test Strip (Urine)

APPLICANT

Company	**Healgen Scientific, LLC**
Location	Houston, TX, US
Contact	Bryan Fang
Website	https://www.healgen.com
510(k) history	27 submissions · 27 cleared · 2012-2026

Healgen Scientific, LLC is a leading in-vitro diagnostics (IVD) developer and manufacturer based in Houston, Texas. Established in 2007, the company specializes in high-quality diagnostic testing technologies across multiple therapeutic areas. Healgen has achieved FDA 510(k) clearances from total submissions since 2012, with no denied submissions on record. The company's regulatory portfolio is dominated by toxicology devices, including drug screening and fentanyl detection products, alongside offerings in chemistry, microbiology, and infectious disease diagnostics. The l...

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k240949/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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