FDA 510(k) Premarket Notification

K241869 BioSieve™ Fentanyl FIA Home Test Kit

CLEARED

Oct 4, 2024
99 days to decision

K241869 · Product code: **NGL** · Toxicology
Source: https://www.510kdatabase.net/k241869/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Opiates, Over The Counter (NGL)
Date received	Jun 27, 2024
Decision date	Oct 4, 2024
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	BioSieve™ Fentanyl FIA Pro Test Kit; BioSieve™ Toxismart Reader

APPLICANT

Company	**Vivachek Biotech (Hangzhou) Co., Ltd.**
Location	Hangzhou, CN
Contact	Max Zhang
510(k) history	9 submissions · 9 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	**LSI International, Inc.**
Contact	Jenny Xia

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov