FDA 510(k) Premarket Notification

K242802 CLUNGENE Fentanyl Home Test Cassette

CLEARED

Nov 8, 2024
52 days to decision

K242802 · Product code: **NGL** · Toxicology
Source: https://www.510kdatabase.net/k242802/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Opiates, Over The Counter (NGL)
Date received	Sep 17, 2024
Decision date	Nov 8, 2024
Days to decision	52 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CLUNGENE Fentanyl Test Cassette

APPLICANT

Company	**Hangzhou Clongene Biotech Co., Ltd.**
Location	Hangzhou, CN
Contact	Frank Zheng
510(k) history	9 submissions · 9 cleared · 2016-2026

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