

K242802 CLUNGENE Fentanyl Home Test CassetteNov 8, 2024
52 days to decisionK242802 · 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](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242802/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026