

K243064 ETERBIO Fentanyl/Norfentanyl Rapid Test (Colloidal Gold)Nov 20, 2024
54 days to decisionK243064 · Product code: **NGL** · Toxicology
Source: <https://www.510kdatabase.net/k243064/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Opiates, Over The Counter (NGL)
Date received	Sep 27, 2024
Decision date	Nov 20, 2024
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary
Other names	ETERBIO Fentanyl/Norfentanyl Home Test

APPLICANT

Company	Eterbio, Inc.
Location	Zhuhai, CN
Contact	Celine Lin
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243064/> 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 14, 2026