

**K241100 Rapid Urine Fentanyl (FYL) Test Strip**May 22, 2024  
30 days to decisionK241100 · Product code: **NGL** · Toxicology  
Source: <https://www.510kdatabase.net/k241100/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Opiates, Over The Counter (NGL)
Date received	Apr 22, 2024
Decision date	May 22, 2024
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Rapid Urine Fentanyl (FYL) Test Dipcard

**APPLICANT**

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Company	<b>Co-Innovation Biotech Co., Ltd.</b>
Location	Guangzhou, Guangdong, CN
Contact	Hong Feng
510(k) history	10 submissions · 10 cleared · 2013-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241100/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026