

**K231904 Rapid Fentanyl (FYL) Test Strip, Rapid Fentanyl (FYL)  
Test Dipcard**Mar 8, 2024  
254 days to decisionK231904 · Product code: **DJG** · Toxicology  
Source: <https://www.510kdatabase.net/k231904/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Jun 28, 2023
Decision date	Mar 8, 2024
Days to decision	254 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**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/k231904/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026