

K242428 Docek® Fentanyl Urine Test Strip, Docek® Fentanyl Urine Test Strip Plus, Docek® Fentanyl Urine Test Card, Docek® Fentanyl Urine Test Card Plus, Docek® Fentanyl Urine Test Cup and Docek® Fentanyl Urine Test Cup Plus

Feb 6, 2025
175 days to decision

K242428 · Product code: **NGL** · Toxicology
Source: <https://www.510kdatabase.net/k242428/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Opiates, Over The Counter (NGL)
Date received	Aug 15, 2024
Decision date	Feb 6, 2025
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Decheng Biotechnology Co., Ltd.
Location	Guangzhou, CN
Contact	Jenny Mao
510(k) history	8 submissions · 8 cleared · 2022-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k242428/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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