

K252554 Wisdiag Multi-Drug Urine Test CupSep 12, 2025
30 days to decisionK252554 · Product code: **NFT** · Toxicology
Source: <https://www.510kdatabase.net/k252554/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Amphetamine, Over The Counter (NFT)
Date received	Aug 13, 2025
Decision date	Sep 12, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Wisdiag Multi-Drug Urine Home Test Cup

APPLICANT

Company	Vivachek Biotech (Hangzhou) Co., Ltd.
Location	Hangzhou, CN
Contact	Chen Qingqing
510(k) history	9 submissions · 9 cleared · 2020-2025

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/k252554/> 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