

K261280 BioSieve Multi-Drug Urine Test PanelMay 22, 2026
35 days to decisionK261280 · Product code: **NFT** · Toxicology
Source: <https://www.510kdatabase.net/k261280/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Amphetamine, Over The Counter (NFT)
Date received	Apr 17, 2026
Decision date	May 22, 2026
Days to decision	35 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	BioSieve Multi-Drug Urine Home Test Panel

APPLICANT

Company	Vivachek Biotech (Hangzhou) Co., Ltd.
Location	Hangzhou, CN
Contact	Qingqing Chen
510(k) history	10 submissions · 10 cleared · 2020-2026

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/k261280/> 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 June 21, 2026