

K240124 BioSieve™ Fentanyl FIA Test KitJun 14, 2024
150 days to decisionK240124 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k240124/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Jan 16, 2024
Decision date	Jun 14, 2024
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	BioSieve™ ToxiSmart FIA Reader

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	LSI International, Inc.
Contact	Joe Shia

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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