

K220046 Superbio Fentanyl Urine Detection Kit, Superbio Immunofluorescence Analyzer EASY-11Dec 13, 2022
342 days to decisionK220046 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k220046/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Jan 5, 2022
Decision date	Dec 13, 2022
Days to decision	342 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Superbio Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Wenhau Yan
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Lsi
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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220046/> 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 26, 2026