

K203647 SEFRIA Methamphetamine Oral Fluid Enzyme ImmunoassayDec 22, 2021
373 days to decisionK203647 · Product code: **LAF** · Toxicology
Source: <https://www.510kdatabase.net/k203647/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gas Chromatography, Methamphetamine (LAF)
Date received	Dec 14, 2020
Decision date	Dec 22, 2021
Days to decision	373 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Immunalysis Corporation
Location	Mchenry, IL, US
Contact	Wenyng (Jessica) Zhu
510(k) history	50 submissions · 50 cleared · 1978-2025

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