

K203564 SEFRIA Oxycodone Oral Fluid Enzyme ImmunoassayDec 22, 2021
380 days to decisionK203564 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k203564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Dec 7, 2020
Decision date	Dec 22, 2021
Days to decision	380 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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