

**K203489 SEFRIA PCP Oral Fluid Enzyme Immunoassay**Apr 20, 2021  
144 days to decisionK203489 · Product code: **LCM** · Toxicology  
Source: <https://www.510kdatabase.net/k203489/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Phencyclidine (LCM)
Date received	Nov 27, 2020
Decision date	Apr 20, 2021
Days to decision	144 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203489/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026