

K181135 Immunoassay SEFRIA PCP Oral Fluid Enzyme ImmunoassayJan 24, 2019
269 days to decisionK181135 · Product code: **LCM** · Toxicology
Source: <https://www.510kdatabase.net/k181135/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Phencyclidine (LCM)
Date received	Apr 30, 2018
Decision date	Jan 24, 2019
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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