

K203527 Immunoanalysis Tapentadol Urine HEIAMay 9, 2022
523 days to decisionK203527 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k203527/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Dec 2, 2020
Decision date	May 9, 2022
Days to decision	523 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lmmunoanalysis Corporation
Location	Pomona, CA, US
Contact	Elina Arroyo
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203527/> 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 27, 2026