

K201089 ARK Lacosamide AssayAug 5, 2021
469 days to decisionK201089 · Product code: **NWM** · Toxicology
Source: <https://www.510kdatabase.net/k201089/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay, Anti-seizure Drug (NWM)
Date received	Apr 23, 2020
Decision date	Aug 5, 2021
Days to decision	469 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	ARK Diagnostics, Inc.
Location	Sunnyvale, CA, US
Contact	Thomas Houts
510(k) history	17 submissions · 16 cleared · 2009-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201089/> 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 26, 2026