

K232522 ARK Levetiracetam II AssayFeb 27, 2024
193 days to decisionK232522 · Product code: **ORI** · Toxicology
Source: <https://www.510kdatabase.net/k232522/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Levetiracetam Assay (ORI)
Date received	Aug 18, 2023
Decision date	Feb 27, 2024
Days to decision	193 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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