

K232017 ARK Methotrexate II AssayDec 20, 2023
166 days to decisionK232017 · Product code: **LAO** · Toxicology
Source: <https://www.510kdatabase.net/k232017/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Methotrexate (LAO)
Date received	Jul 7, 2023
Decision date	Dec 20, 2023
Days to decision	166 days
Third-party review	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/k232017/> 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 13, 2026