FDA 510(k) Premarket Notification

K232017 ARK Methotrexate II Assay

CLEARED

Dec 20, 2023
166 days to decision

K232017 · 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