

K163359 ARK Methotrexate AssayAug 18, 2017
261 days to decisionK163359 · Product code: **LAO** · Toxicology
Source: <https://www.510kdatabase.net/k163359/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Methotrexate (LAO)
Date received	Nov 30, 2016
Decision date	Aug 18, 2017
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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