

K101305 ARK LAMOTRIGINE ASSAY, CALIBRATOR & CONTROLOct 29, 2010
172 days to decisionK101305 · Product code: **ORH** · Toxicology
Source: <https://www.510kdatabase.net/k101305/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lamotrigine Assay (ORH)
Date received	May 10, 2010
Decision date	Oct 29, 2010
Days to decision	172 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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