

**K083799 TOPIRAMATE ASSAY, ARK TOPIRAMATE
CALBRATOR AND ARK TOPIRAMATE CONTROL, MODELS
5015-0001-000, 5015-0002-00, 5015-0003-00**Apr 16, 2009
115 days to decisionK083799 · Product code: **NWM** · Toxicology
Source: <https://www.510kdatabase.net/k083799/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay, Anti-seizure Drug (NWM)
Date received	Dec 22, 2008
Decision date	Apr 16, 2009
Days to decision	115 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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