

K091884 ARK ZONISAMIDE ASSAY, ARK ZONISAMIDE CALIBRATOR, AND ARK ZONISAMIDE CONTRO, MODELS 5022-0001-00, 5022-0002-00, 5022-0003Dec 9, 2009
168 days to decisionK091884 · Product code: **NWM** · Toxicology
Source: <https://www.510kdatabase.net/k091884/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay, Anti-seizure Drug (NWM)
Date received	Jun 24, 2009
Decision date	Dec 9, 2009
Days to decision	168 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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