

**K091653 ARK LEVETIRACETAM ASSAY, ARK LEVETIRACETAM CALIBRATOR AND ARK LEVETIRACETAM CONTROL, MODELS 5024-0001-00, 5024-0002-00**

Nov 2, 2009  
146 days to decision

K091653 · Product code: **ORI** · Toxicology  
Source: <https://www.510kdatabase.net/k091653/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Levetiracetam Assay (ORI)
Date received	Jun 9, 2009
Decision date	Nov 2, 2009
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k091653/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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