CLEARED

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

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

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