

K101574 ARK GABAPENTIN ASSAY, ARK GABEPENTIN CALIFRATOR, AND ARK GABAPENTIN CONTROL MODEL5025-0001-00, 5025-0002-00, 5025-0003-0Nov 23, 2010
169 days to decisionK101574 · Product code: **OTF** · Toxicology
Source: <https://www.510kdatabase.net/k101574/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gabapentin Assay (OTF)
Date received	Jun 7, 2010
Decision date	Nov 23, 2010
Days to decision	169 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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