

K231752 ARK Hydrocodone AssayNov 9, 2023
147 days to decisionK231752 · Product code: **DJG** · Chemistry
Source: <https://www.510kdatabase.net/k231752/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Jun 15, 2023
Decision date	Nov 9, 2023
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	ARK Diagnostics, Inc.
Location	Sunnyvale, CA, US
Contact	Thomas Houts, Ph.D
510(k) history	17 submissions · 16 cleared · 2009-2024

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