

**K182280 ARK Tramadol Assay**Dec 10, 2018  
110 days to decisionK182280 · Product code: **DJG** · Toxicology  
Source: <https://www.510kdatabase.net/k182280/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Aug 22, 2018
Decision date	Dec 10, 2018
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>ARK Diagnostics, Inc.</b>
Location	Sunnyvale, CA, US
Contact	Cherry Mun
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/k182280/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026