

K200197 ARK Fentanyl II AssayFeb 26, 2020
30 days to decisionK200197 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k200197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Jan 27, 2020
Decision date	Feb 26, 2020
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200197/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026