

K180427 ARK Fentanyl AssayJun 6, 2018
110 days to decisionK180427 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k180427/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Feb 16, 2018
Decision date	Jun 6, 2018
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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