

K221550 Evidence MultiSTAT DOA Urine MultiPlexOct 5, 2023
492 days to decisionK221550 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k221550/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	May 31, 2022
Decision date	Oct 5, 2023
Days to decision	492 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Randox Laboratories Limited
Location	Crumlin, GB
Contact	Karena Shaw
510(k) history	18 submissions · 18 cleared · 2004-2026

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