

**K110846 RANDOX URINALYSIS CONTROLS, LEVELS 1 AND 2**Sep 30, 2011  
186 days to decisionK110846 · Product code: **JJW** · Chemistry  
Source: <https://www.510kdatabase.net/k110846/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urinalysis Controls (assayed And Unassayed) (JJW)
Date received	Mar 28, 2011
Decision date	Sep 30, 2011
Days to decision	186 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Radox Laboratories Limited</b>
Location	Crumlin, GB
Contact	PAULINE ARMSTRONG
510(k) history	18 submissions · 18 cleared · 2004-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110846/> 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 25, 2026