

**K112337 RANDOX LIQUID IMMUNOASSAY PREMIUM CONTROLS, LEVEL 1, LEVEL2, LEVEL 3 AND TRI LEVEL**Dec 1, 2011  
108 days to decisionK112337 · Product code: JJY · Chemistry  
Source: <https://www.510kdatabase.net/k112337/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Aug 15, 2011
Decision date	Dec 1, 2011
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Radox Laboratories, Ltd.</b>
Location	Antrim, N. Ireland, IR
Contact	PAULINE ARMSTRONG
Website	<a href="http://www.radox.com/">http://www.radox.com/</a>
510(k) history	116 submissions · 115 cleared · 1992-2025

Radox Laboratories, Ltd. is a global diagnostic company specializing in chemistry devices and laboratory solutions. The company operates with a manufacturing facility in Antrim, Northern Ireland, and has over 40 years of expertise in diagnostic innovation. Radox has received FDA 510(k) clearances from total submissions since its first clearance in 1992. The company's regulatory portfolio is dominated by chemistry devices, including clinical chemistry analyzers, reagents, controls, and electrodes. The latest clearance on record dates to 2023. Recent FDA 510(k) cleared de...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k112337/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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