

**K110534 RANDOX LIQUID CARDIAC CONTROL LEVELS 1, 2
AND 3**Jan 23, 2012
332 days to decisionK110534 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k110534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Feb 25, 2011
Decision date	Jan 23, 2012
Days to decision	332 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110534/> 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 25, 2026