

K130337 RANDOX SPECIALITY CONTROL (I) LEVELS 1, 2 AND 3Jun 19, 2013
128 days to decisionK130337 · Product code: **JJY** · Immunology
Source: <https://www.510kdatabase.net/k130337/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Feb 11, 2013
Decision date	Jun 19, 2013
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

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/k130337/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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