

K041361 RANDOX TRI LEVEL CARDIAC CONTROLSep 9, 2004
111 days to decisionK041361 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k041361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	May 21, 2004
Decision date	Sep 9, 2004
Days to decision	111 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

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