

K113747 RANDOX OPIATES ASSAYAug 24, 2012
248 days to decisionK113747 · Product code: **DJG** · Chemistry
Source: <https://www.510kdatabase.net/k113747/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Dec 20, 2011
Decision date	Aug 24, 2012
Days to decision	248 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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