

**K040379 RANDOX IMMUNOASSAY CONTROL**Jun 16, 2004  
120 days to decisionK040379 · Product code: **JJY** · Chemistry  
Source: <https://www.510kdatabase.net/k040379/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Feb 17, 2004
Decision date	Jun 16, 2004
Days to decision	120 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Radox Laboratories, Ltd.</b>
Location	Antrim, N. Ireland, IR
Contact	P. 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...

---