

**K131999 HBA1C CONTROL, LEVEL 1 AND LEVEL 2**Jul 26, 2013  
28 days to decisionK131999 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k131999/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jun 28, 2013
Decision date	Jul 26, 2013
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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