

**K102346 RANDOX DIGOXIN ASSAY**Oct 14, 2011  
421 days to decisionK102346 · Product code: **KXT** · Chemistry  
Source: <https://www.510kdatabase.net/k102346/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Enzyme Immunoassay, Digoxin (KXT)  |
| Date received         | Aug 19, 2010                       |
| Decision date         | Oct 14, 2011                       |
| Days to decision      | 421 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**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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