

K131776 ALDOLASE CONTROLS LEVEL 2, AND ALDOLASE CONTROL LEVEL 3Jul 18, 2013
31 days to decisionK131776 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k131776/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Single (specified) Analyte Controls (assayed And Unassayed) (JJX) |
| Date received | Jun 17, 2013 |
| Decision date | Jul 18, 2013 |
| Days to decision | 31 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Radox Laboratories, Ltd. |
| Location | Antrim, N. Ireland, IR |
| Contact | PAULINE ARMSTRONG |
| Website | http://www.radox.com/ |
| 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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Device record: <https://www.510kdatabase.net/k131776/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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