

K031608 RANDOX LIQUID PROTEIN CALIBRATORAug 8, 2003
78 days to decisionK031608 · Product code: **JIX** · Chemistry
Source: <https://www.510kdatabase.net/k031608/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Calibrator, Multi-analyte Mixture (JIX) |
| Date received | May 22, 2003 |
| Decision date | Aug 8, 2003 |
| Days to decision | 78 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Radox Laboratories, Ltd. |
| Location | Antrim, N. Ireland, IR |
| Contact | P. 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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k031608/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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