

K000662 RANDOX FERRITINApr 3, 2000
35 days to decisionK000662 · Product code: **DBF** · Immunology
Source: <https://www.510kdatabase.net/k000662/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ferritin, Antigen, Antiserum, Control (DBF) |
| Date received | Feb 28, 2000 |
| Decision date | Apr 3, 2000 |
| Days to decision | 35 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...
