

K961169 RHEUMATOID FACTOR LATEX SLIDE TEST KITJun 26, 1996
93 days to decisionK961169 · Product code: **DHR** · Immunology
Source: <https://www.510kdatabase.net/k961169/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Rheumatoid Factor (DHR) |
| Date received | Mar 25, 1996 |
| Decision date | Jun 26, 1996 |
| Days to decision | 93 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Randox Laboratories, Ltd. |
| Location | Antrim, N. Ireland, IR |
| Contact | P. ARMSTRONG |
| Website | http://www.randox.com/ |
| 510(k) history | 116 submissions · 115 cleared · 1992-2025 |

Randox 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. Randox 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...