

K951222 TOTAL PROTEIN (URINE)Apr 24, 1996
401 days to decisionK951222 · Product code: **JIR** · Chemistry
Source: <https://www.510kdatabase.net/k951222/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Indicator Method, Protein Or Albumin (urinary, Non-quant.) (JIR) |
| Date received | Mar 20, 1995 |
| Decision date | Apr 24, 1996 |
| Days to decision | 401 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Randox Laboratories, Ltd. |
| Location | Antrim, N. Ireland, IR |
| Contact | John Lamont |
| 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...
