

**K131554 RX DAYTONA PLUS CHEMISTRY ANALYZER**Jan 9, 2014  
224 days to decisionK131554 · Product code: **JJE** · Chemistry  
Source: <https://www.510kdatabase.net/k131554/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Chemistry (photometric, Discrete), For Clinical Use (JJE)
Date received	May 30, 2013
Decision date	Jan 9, 2014
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary
Other names	RX DAYTONA PLUS ASPARTATE AMINOTRANSFERASE (AST) REAGENT

**APPLICANT**

---

Company	<b>Randox Laboratories, Ltd.</b>
Location	Antrim, N. Ireland, IR
Contact	PAULINE ARMSTRONG
Website	<a href="http://www.randox.com/">http://www.randox.com/</a>
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...