

**K973995 RANDOX BILIRUBIN**Dec 8, 1997  
48 days to decisionK973995 · Product code: **GIG** · Chemistry  
Source: <https://www.510kdatabase.net/k973995/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobinometer (GIG)
Date received	Oct 21, 1997
Decision date	Dec 8, 1997
Days to decision	48 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---