

K950383 APOLIPOPROTEIN A-I IMMUNOTURBIDIMETRIC KITSep 15, 1995
227 days to decisionK950383 · Product code: **JHN** · Chemistry
Source: <https://www.510kdatabase.net/k950383/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Turbidimetric Method, Lipoproteins (JHN)
Date received	Jan 31, 1995
Decision date	Sep 15, 1995
Days to decision	227 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...

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