

K153435 Direct HDL Cholesterol (HDL)Jan 8, 2016
42 days to decisionK153435 · Product code: **LBS** · Chemistry
Source: <https://www.510kdatabase.net/k153435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Nov 27, 2015
Decision date	Jan 8, 2016
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Randox Laboratories, Ltd.
Location	Antrim, N. Ireland, IR
Contact	Pauline 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...

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