

**K970735 BOEHRINGER MANNHEIM DIRECT HDL-  
CHOLESTEROL**Jun 6, 1997  
108 days to decisionK970735 · Product code: **LBS** · Chemistry  
Source: <https://www.510kdatabase.net/k970735/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Feb 18, 1997
Decision date	Jun 6, 1997
Days to decision	108 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Radox Laboratories, Ltd.</b>
Location	Antrim, N. Ireland, IR
Contact	P. ARMSTONG
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...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k970735/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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