

K161691 Direct LDL Cholesterol (LDL)Mar 20, 2017
273 days to decisionK161691 · Product code: **MRR** · Chemistry
Source: <https://www.510kdatabase.net/k161691/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Low Density, Lipoprotein (MRR)
Date received	Jun 20, 2016
Decision date	Mar 20, 2017
Days to decision	273 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Radox Laboratories Limited
Location	Crumlin, GB
Contact	PAULINE ARMSTRONG
510(k) history	18 submissions · 18 cleared · 2004-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161691/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026