

K143691 LDLC3 LDL-Cholesterol Gen.3Jan 28, 2015
35 days to decisionK143691 · Product code: **LBR** · Chemistry
Source: <https://www.510kdatabase.net/k143691/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Hdl (LBR)
Date received	Dec 24, 2014
Decision date	Jan 28, 2015
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Operations (Rdo)
Location	Indianapolis, IN, US
Contact	Noel B Mencias
510(k) history	14 submissions · 14 cleared · 2014-2020

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