

K162593 HDL-Cholesterol Gen.4Oct 19, 2016
33 days to decisionK162593 · Product code: **LBS** · Chemistry
Source: <https://www.510kdatabase.net/k162593/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Sep 16, 2016
Decision date	Oct 19, 2016
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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