

K050632 ADVIA IMS DIRECT HDL CHOLESTEROL ASSAYMay 26, 2005
78 days to decisionK050632 · Product code: **LBS** · Chemistry
Source: <https://www.510kdatabase.net/k050632/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Mar 9, 2005
Decision date	May 26, 2005
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Healthcare, LLC
Location	New York, NY, US
Contact	ANDRES HOLLE
510(k) history	46 submissions · 46 cleared · 2003-2018

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