

**K012286 MODIFICATION TO:COBAS INTEGRA HDL-
CHOLESTEROL PLUS 2ND GENERATION**Aug 8, 2001
19 days to decisionK012286 · Product code: **LBS** · Chemistry
Source: <https://www.510kdatabase.net/k012286/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Jul 20, 2001
Decision date	Aug 8, 2001
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	SHERRI L COENEN
510(k) history	264 submissions · 263 cleared · 1999-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012286/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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