

**K012287 MODIFICATION TO: COBAS INTEGRA LDL-  
CHOLESTEROL PLUS 2ND GENERATION**Aug 7, 2001  
18 days to decisionK012287 · Product code: MRR · Chemistry  
Source: <https://www.510kdatabase.net/k012287/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Low Density, Lipoprotein (MRR)
Date received	Jul 20, 2001
Decision date	Aug 7, 2001
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012287/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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