

**K982848 COBAS INTEGRA LDL DIRECT REAGENT CASSETTE
ROCHE CALIBRATOR LDL DIRECT**Oct 1, 1998
50 days to decisionK982848 · Product code: MRR · Chemistry
Source: <https://www.510kdatabase.net/k982848/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Low Density, Lipoprotein (MRR)
Date received	Aug 12, 1998
Decision date	Oct 1, 1998
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	MARIA FEIJOO
510(k) history	296 submissions · 296 cleared · 1983-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k982848/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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