

K973369 ROCHE UNIMATE HDL DIRECT REAGEN (WITH POL CLAIM)Nov 21, 1997
74 days to decisionK973369 · Product code: LBR · Chemistry
Source: <https://www.510kdatabase.net/k973369/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Hdl (LBR)
Date received	Sep 8, 1997
Decision date	Nov 21, 1997
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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