

K971902 ROCHE UNIMATE HDL DIRECT REAGENT, ROCHE CALIBRATOR HDL DIRECTJun 16, 1997
24 days to decisionK971902 · Product code: **LBS** · Chemistry
Source: <https://www.510kdatabase.net/k971902/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	May 23, 1997
Decision date	Jun 16, 1997
Days to decision	24 days
Third-party review	No
Summary / Statement	Statement

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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