

**K974342 ROCHE COBAS AMPLICOR CT/NG TEST FOR
NEISSERIA GONORRHOEAE**May 28, 1999
556 days to decisionK974342 · Product code: LSL · Microbiology
Source: <https://www.510kdatabase.net/k974342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-reagents, Neisseria (LSL)
Date received	Nov 18, 1997
Decision date	May 28, 1999
Days to decision	556 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Molecular Systems, Inc.
Location	Somerville, NJ, US
Contact	ALEX WESOLOWSKI
510(k) history	51 submissions · 48 cleared · 1993-2026

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