

**K974503 ROCHE AMPLICOR CT/NG TEST FOR NEISSERIA
GONORRHOEAE**Dec 1, 1999
733 days to decisionK974503 · Product code: **LSL** · Microbiology
Source: <https://www.510kdatabase.net/k974503/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-reagents, Neisseria (LSL)
Date received	Nov 28, 1997
Decision date	Dec 1, 1999
Days to decision	733 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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