

**K973718 ROCHE COBAS AMPLICOR CT/NG TEST FOR CHLAMYDIA TRACHOMATIS**Dec 15, 1998  
442 days to decisionK973718 · Product code: **MKZ** · Microbiology  
Source: <https://www.510kdatabase.net/k973718/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna Probe, Nucleic Acid Amplification, Chlamydia (MKZ)
Date received	Sep 29, 1997
Decision date	Dec 15, 1998
Days to decision	442 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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