

**K964507 ROCHE COBAS AMPLICOR CHLAMYDIA  
TRACHOMATIS TEST**Jun 13, 1997  
217 days to decisionK964507 · Product code: **MKZ** · Microbiology  
Source: <https://www.510kdatabase.net/k964507/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna Probe, Nucleic Acid Amplification, Chlamydia (MKZ)
Date received	Nov 8, 1996
Decision date	Jun 13, 1997
Days to decision	217 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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