

K973707 ROCHE AMPLICOR CT/NG TEST FOR CHLAMYDIA TRACHOMATISAug 4, 1999
674 days to decisionK973707 · Product code: **MKZ** · Microbiology
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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	Aug 4, 1999
Days to decision	674 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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