

K053287 COBAS AMPLICOR CT/NG TEST FOR CHLAMYDIA TRACHOMATISAug 10, 2006
258 days to decisionK053287 · Product code: **MKZ** · Microbiology
Source: <https://www.510kdatabase.net/k053287/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna Probe, Nucleic Acid Amplification, Chlamydia (MKZ)
Date received	Nov 25, 2005
Decision date	Aug 10, 2006
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	THERESA M AMBROSE
510(k) history	264 submissions · 263 cleared · 1999-2013

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