

K110923 COBAS 4800 CT / NG TESTJan 24, 2012
298 days to decisionK110923 · Product code: **MKZ** · Microbiology
Source: <https://www.510kdatabase.net/k110923/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna Probe, Nucleic Acid Amplification, Chlamydia (MKZ)
Date received	Apr 1, 2011
Decision date	Jan 24, 2012
Days to decision	298 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Molecular Systems, Inc.
Location	Somerville, NJ, US
Contact	JAMES BONDS
510(k) history	51 submissions · 48 cleared · 1993-2026

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