

K070174 AMPLICOR CT/NG TEST FOR CHLAMYDIA TRACHOMATISApr 16, 2007
88 days to decisionK070174 · Product code: **MKZ** · Microbiology
Source: <https://www.510kdatabase.net/k070174/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dna Probe, Nucleic Acid Amplification, Chlamydia (MKZ) |
| Date received | Jan 18, 2007 |
| Decision date | Apr 16, 2007 |
| Days to decision | 88 days |
| Third-party review | No |
| Summary / Statement | Summary |
| Other names | ROCHE SCRIPTS FOR CT/NG TEST ACCESSORY |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Roche Diagnostics Corporation |
| Location | Indianapolis, IN, US |
| Contact | THERESA AMBROSE BUSH |
| 510(k) history | 6 submissions · 6 cleared · 2007-2015 |

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