

**K070172 AMPLICOR CT/NG TEST FOR NEISSERIA  
GONORRHOEAE**Apr 17, 2007  
89 days to decisionK070172 · Product code: **LSL** · Microbiology  
Source: <https://www.510kdatabase.net/k070172/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-reagents, Neisseria (LSL)
Date received	Jan 18, 2007
Decision date	Apr 17, 2007
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k070172/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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