

**K003395 GEN-PROBE APTIMA COMBO 2 ASSAY**May 21, 2001  
201 days to decisionK003395 · Product code: **LSL** · Microbiology  
Source: <https://www.510kdatabase.net/k003395/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-reagents, Neisseria (LSL)
Date received	Nov 1, 2000
Decision date	May 21, 2001
Days to decision	201 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Gen-Probe, Inc.</b>
Location	San Diego, CA, US
Contact	E. JOSEPH MCMULLEN
Website	<a href="http://www.gen-probe.com">http://www.gen-probe.com</a>
510(k) history	62 submissions · 62 cleared · 1985-2013

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