

K163184 cobas® CT/NG v2.0 TestFeb 9, 2017
87 days to decisionK163184 · Product code: **LSL** · Microbiology
Source: <https://www.510kdatabase.net/k163184/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-reagents, Neisseria (LSL)
Date received	Nov 14, 2016
Decision date	Feb 9, 2017
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Molecular Systems, Inc.
Location	Somerville, NJ, US
Contact	David W. Gates
510(k) history	49 submissions · 46 cleared · 1993-2025

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