

K240217 cobas® liat CT/NG nucleic acid testJan 17, 2025
357 days to decisionK240217 · Product code: **QEP** · Microbiology
Source: <https://www.510kdatabase.net/k240217/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Nucleic Acid Detection System For Non-viral Microorganism(s) Causing Sexually Transmitted Infections (QEP)
Date received	Jan 26, 2024
Decision date	Jan 17, 2025
Days to decision	357 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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