

**K213804 cobas SARS-CoV-2 Qualitative for use on the cobas 6800/8800 Systems**Oct 22, 2022  
320 days to decisionK213804 · Product code: **QQX** · Microbiology  
Source: <https://www.510kdatabase.net/k213804/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Specimen Nucleic Acid Sars-cov-2 Test (QQX)
Date received	Dec 6, 2021
Decision date	Oct 22, 2022
Days to decision	320 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Molecular Systems, Inc.</b>
Location	Somerville, NJ, US
Contact	Rita Hoady
510(k) history	49 submissions · 46 cleared · 1993-2025

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