

K231306 cobas SARS-CoV-2 Qualitative for use on the cobas 5800/6800/8800 SystemsJun 1, 2023
27 days to decisionK231306 · Product code: **QQX** · Microbiology
Source: <https://www.510kdatabase.net/k231306/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Respiratory Specimen Nucleic Acid Sars-cov-2 Test (QQX)
Date received	May 5, 2023
Decision date	Jun 1, 2023
Days to decision	27 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	Caroline Sobek
510(k) history	49 submissions · 46 cleared · 1993-2025

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