

K223783 cobas SARS-CoV-2 Nucleic acid test for use on the cobas Liat SystemDec 4, 2023
353 days to decisionK223783 · Product code: **QWR** · Microbiology
Source: <https://www.510kdatabase.net/k223783/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Simple Point-of-care Device To Detect Sar-cov-2 Nucleic Acid Targets From Clinical Specimens In Near-patient Settings (QWR)
Date received	Dec 16, 2022
Decision date	Dec 4, 2023
Days to decision	353 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	Aradhana Karthikeyan
510(k) history	49 submissions · 46 cleared · 1993-2025

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