

K210234 cobas Influenza A/B & RSV Nucleic acid test for use on the cobas Liat SystemFeb 16, 2021
19 days to decisionK210234 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k210234/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Jan 28, 2021
Decision date	Feb 16, 2021
Days to decision	19 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	Kaitlyn Hameister
510(k) history	49 submissions · 46 cleared · 1993-2025

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