

K200065 cobas Influenza A/B Nucleic acid test for use on the cobas Liat System, cobas Influenza A/B & RSV Nucleic acid test for use on the cobas Liat System, cobas Strep A Nucleic acid test for use on the cobas Liat System

Feb 10, 2020
28 days to decision

K200065 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k200065/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Jan 13, 2020
Decision date	Feb 10, 2020
Days to decision	28 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	51 submissions · 48 cleared · 1993-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k200065/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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