

K191729 Cobas Influenza A/B Nucleic Acid Test for Use on the Cobas Liat SystemJul 24, 2019
27 days to decisionK191729 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k191729/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Jun 27, 2019
Decision date	Jul 24, 2019
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	Kaitlyn Hameister
510(k) history	51 submissions · 48 cleared · 1993-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191729/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026