

K163266 Alere i Influenza A & B, Alere i Influenza A & B Control Swab Kit, Alere i InstrumentDec 21, 2016
30 days to decisionK163266 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k163266/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Nov 21, 2016
Decision date	Dec 21, 2016
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alere Scarborough, Inc.
Location	Scarborough, ME, US
Contact	Angela Drysdale
510(k) history	17 submissions · 16 cleared · 2012-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163266/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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