

K161375 Alere i RSV, Alere i Instrument, Alere i RSV Control Swab KitAug 18, 2016
92 days to decisionK161375 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k161375/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	May 18, 2016
Decision date	Aug 18, 2016
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161375/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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