

K151464 Alere i Influenza A & B, Alere i Instrument, Alere i Influenza A & B Control Swab Kit

Jul 28, 2015
57 days to decision

K151464 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k151464/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Jun 1, 2015
Decision date	Jul 28, 2015
Days to decision	57 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.net

Device record: <https://www.510kdatabase.net/k151464/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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