

K141520 ALERE I INFLUENZA A & BJun 13, 2014
4 days to decisionK141520 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k141520/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Jun 9, 2014
Decision date	Jun 13, 2014
Days to decision	4 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alere Scarborough, Inc D/B/A Binax, Inc.
Location	Scarborough, ME, US
Contact	Angela Drysdale
510(k) history	4 submissions · 4 cleared · 2011-2014

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