

K133637 ALERE INFLUENZA A & B TESTDec 18, 2013
41 days to decisionK133637 · Product code: **PSZ** · Microbiology
Source: <https://www.510kdatabase.net/k133637/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Nov 7, 2013
Decision date	Dec 18, 2013
Days to decision	41 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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