

**K162642 Alere BinaxNOW Influenza A & B Card 2, Alere Reader,  
Alere BinaxNOW Influenza A & B Card 2 Control Swab Kit**

Apr 10, 2017  
200 days to decision

K162642 · Product code: **PSZ** · Microbiology  
Source: <https://www.510kdatabase.net/k162642/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Sep 22, 2016
Decision date	Apr 10, 2017
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Alere Scarborough, Inc.</b>
Location	Scarborough, ME, US
Contact	SARA HALLOWELL
510(k) history	17 submissions · 16 cleared · 2012-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k162642/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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