

**K173502 Alere BinaxNOW Influenza A & B Card 2, Alere Reader,
Alere BinaxNOW Influenza A & B Card 2 Control Swab Kit**

Dec 13, 2017
30 days to decision

K173502 · Product code: **PSZ** · Microbiology
Source: <https://www.510kdatabase.net/k173502/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Nov 13, 2017
Decision date	Dec 13, 2017
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k173502/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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