

**K181853 Alere BinaxNOW Influenza A & B Card 2, Alere Reader**Aug 8, 2018  
28 days to decisionK181853 · Product code: **PSZ** · Microbiology  
Source: <https://www.510kdatabase.net/k181853/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Jul 11, 2018
Decision date	Aug 8, 2018
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181853/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026