

**K133411 ALERE BINAXNOW INFLUENZA A & B CARD**Dec 5, 2013  
28 days to decisionK133411 · Product code: **GNX** · Microbiology  
Source: <https://www.510kdatabase.net/k133411/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Antigens, Cf (including Cf Control), Influenza Virus A, B, C (GNX)
Date received	Nov 7, 2013
Decision date	Dec 5, 2013
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133411/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 6, 2026