

**K062109 BINAXNOW INFLUENZA A & B TEST**Nov 9, 2006  
108 days to decisionK062109 · Product code: **PSZ** · Microbiology  
Source: <https://www.510kdatabase.net/k062109/>**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	Jul 24, 2006
Decision date	Nov 9, 2006
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Binax, Inc.</b>
Location	S. Portland, ME, US
Contact	Angela Drysdale
510(k) history	30 submissions · 30 cleared · 1986-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062109/> 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 21, 2026