

K092223 MODIFICATION TO: BINAXNOW INFLUENZA A & B TESTAug 12, 2009
20 days to decisionK092223 · Product code: **PSZ** · Microbiology
Source: <https://www.510kdatabase.net/k092223/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Jul 23, 2009
Decision date	Aug 12, 2009
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092223/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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