

K090301 BINAXNOW PBP2A TEST, MODEL 890-000Apr 14, 2010
432 days to decisionK090301 · Product code: **MYI** · Microbiology
Source: <https://www.510kdatabase.net/k090301/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Genotypic Detection, Resistant Markers, Staphylococcus Colonies (MYI)
Date received	Feb 6, 2009
Decision date	Apr 14, 2010
Days to decision	432 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090301/> 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 21, 2026