

**K982238 BINAX NOW LEGIONELLA URINARY ANTIGEN TEST
 MODEL 852-020 AND BINAX NOW LEG IONELLA URINARY
 ANTIGEN CONTROL KIT MODEL 8522**

Aug 21, 1998
 57 days to decision

K982238 · Product code: **MJH** · Microbiology
 Source: <https://www.510kdatabase.net/k982238/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Legionella, Spp., Elisa (MJH)
Date received	Jun 25, 1998
Decision date	Aug 21, 1998
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k982238/> 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