

**K991726 BINAX NOWR STREPTOCOCCUS PNEUMONIAE
URINARY ANTIGEN TEST (22 TEST KIT),(12 TEST KIT), BINAX
NOWR STREPTOCOCCUS PNEUMONI**

Aug 27, 1999
99 days to decision

K991726 · Product code: **GTZ** · Microbiology
Source: <https://www.510kdatabase.net/k991726/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	May 20, 1999
Decision date	Aug 27, 1999
Days to decision	99 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/k991726/> 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