

**K010523 MODIFICATION TO BINAX NOW STREPTOCOCCUS
PNEUMONIAE URINARY ANTIGEN TEST**Mar 15, 2001
21 days to decisionK010523 · Product code: **GTZ** · Microbiology
Source: <https://www.510kdatabase.net/k010523/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Feb 22, 2001
Decision date	Mar 15, 2001
Days to decision	21 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

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