

**K991828 STREP B OIA**Aug 19, 1999  
83 days to decisionK991828 · Product code: **GTY** · Microbiology  
Source: <https://www.510kdatabase.net/k991828/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	May 28, 1999
Decision date	Aug 19, 1999
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biostar, Inc.</b>
Location	Boulder, CO, US
Contact	ROGER C BRIDEN
510(k) history	6 submissions · 6 cleared · 1994-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k991828/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026