

**K936112 STREP B OIA**Jul 6, 1994  
195 days to decisionK936112 · Product code: **GTY** · Microbiology  
Source: <https://www.510kdatabase.net/k936112/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Dec 23, 1993
Decision date	Jul 6, 1994
Days to decision	195 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Biostar, Inc.</b>
Location	Boulder, CO, US
Contact	DAN W CHILDERS
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/k936112/> 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