

**K962060 STREP A OIA MAX**Jul 23, 1997  
421 days to decisionK962060 · Product code: **GTZ** · Microbiology  
Source: <https://www.510kdatabase.net/k962060/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	May 28, 1996
Decision date	Jul 23, 1997
Days to decision	421 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Biostar, Inc.</b>
Location	Boulder, CO, US
Contact	LYNDAL K HESTERBERG
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/k962060/> 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