

**K912889 OIA STREP A**Oct 31, 1991  
122 days to decisionK912889 · Product code: **GTZ** · Microbiology  
Source: <https://www.510kdatabase.net/k912889/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Jul 1, 1991
Decision date	Oct 31, 1991
Days to decision	122 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Biosearch Medical Products, Inc.</b>
Location	Mchenry, IL, US
Contact	DONALD L MEYER
510(k) history	70 submissions · 66 cleared · 1978-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k912889/> 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 30, 2026