

**K842827 STREPTEX DIRECT A ZL14**Aug 16, 1984  
27 days to decisionK842827 · Product code: **GTZ** · Immunology  
Source: <https://www.510kdatabase.net/k842827/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Jul 20, 1984
Decision date	Aug 16, 1984
Days to decision	27 days
Third-party review	No

**APPLICANT**

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Company	<b>Wellcome Diagnostics</b>
Location	Walker, MI, US
510(k) history	28 submissions · 28 cleared · 1983-1992

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Device record: <https://www.510kdatabase.net/k842827/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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